BEFORE THE
INTELLECTUAL PROPERTY AND INDUSTRY SUBCOMMITTEE
TO 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: JANUARY 26, 2017
10 A.M.

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

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THURSDAY, JANUARY 26, 2017

10 A.M.

CHAIRMAN JUELSGAARD: VERY GOOD. I AM READY TO START. SO I'D LIKE TO CONVENE THE MEETING OF THE INTELLECTUAL PROPERTY SUBCOMMITTEE OF THE ICOC. WOULD YOU CALL THE ROLL PLEASE.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: STEVE JUELSGAARD.

CHAIRMAN JUELSGAARD: HERE.

MS. BONNEVILLE: JOE PANETTA.

MR. PANETTA: HERE.

MS. BONNEVILLE: JEFF SHEEHY. OS STEWARD.

DR. STEWARD: HERE.

MS. BONNEVILLE: JONATHAN THOMAS.

CHAIRMAN THOMAS: HERE.

MS. BONNEVILLE: STEVE, WE HAVE A QUORUM. JEFF, I'M SURE, WILL JOIN.

CHAIRMAN JUELSGAARD: PERFECT. THANKS SO MUCH, MARIA.

SO THE PURPOSE OF THIS MEETING, I ASSUME YOU'VE ALL RECEIVED FROM AMY THE AGENDA FOR TODAY, BUT WE HAVE A PARTICULAR PURPOSE. AND THAT'S TO CONSIDER CHANGES TO THE DETERMINATION OF REVENUE

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THAT CIRM MIGHT RECEIVE IN THE FUTURE FROM PRODUCTS THAT IT HAS FUNDED SOMEWHERE ALONG THE WAY. FOR THOSE OF YOU THAT HAVE BEEN THROUGH THE EXISTING REGULATIONS, IT'S A BIT OF A RABBIT HOLE TO FOLLOW ALONG, BUT SCOTT AND BEN, AND THEY MAY HAVE HAD SOME HELP FROM OTHERS, HAVE MADE AN EFFORT TO TRY AND SIMPLIFY ALL OF THIS. SO I'M GOING TO TURN THE DISCUSSION OVER TO SCOTT TO DESCRIBE SOME PROPOSED CHANGES TO THE WAY REVENUE WHICH WOULD BE USED TO CALCULATE RETURN TO CIRM CHANGES TO THE WAY THAT REVENUE MIGHT BE CALCULATED. SO, SCOTT, ARE YOU THERE?

MR. TOCHER: I AM. THANK YOU, STEVE.

MR. SHEEHY: I JUST WANTED TO LET YOU GUYS KNOW. THIS IS JEFF SHEEHY. I'M HERE.

MS. BONNEVILLE: THANK YOU, JEFF.

MR. TOCHER: I WILL PROCEED WITH THE SLIDE PRESENTATION THAT HAS BEEN SENT TO YOU THAT IS AVAILABLE, THE LINK, IN AMY'S E-MAIL. IT'S ALSO ON OUR WEBSITE. BUT IF YOU'RE FOLLOWING ON WEBEX, YOU CAN JUST WATCH, AND I WILL ADVANCE THE SLIDES THROUGH THE DISCUSSION.

SO AS STEVE ALLUDED, WE ARE HERE TODAY BECAUSE, AS PART OF CIRM 2.0, DR. MILLS HAS CHALLENGED THE CIRM TEAM TO EXAMINE ALL PARTS OF

CIRM'S OPERATIONS, BOTH INTERNALLY FACING AND EXTERNALLY FACING, TO IDENTIFY OPPORTUNITIES TO BETTER ACHIEVE CIRM'S MISSION. TO THAT END, THE LEGAL TEAM, CONSISTING OV ME AND BEN HUANG AND JAMES HARRISON, LOOKED CLOSELY AT OUR IP REGULATIONS. AND TODAY WE'D LIKE TO SHARE SOME IDEAS FOR MOVING FORWARD.

WHEN WE CONSIDER RULES GOVERNING INTELLECTUAL PROPERTY THAT'S CREATED WITH CIRM FUNDING, WE START WITH PROPOSITION 71'S CHARGE, WHICH IS TO STRIKE A BALANCE BETWEEN THE OPPORTUNITY FOR THE STATE TO BENEFIT FROM LICENSING REVENUES AND ROYALTIES VERSUS THE NEED TO ENSURE THAT THESE REQUIREMENTS DO NOT UNREASONABLY HINDER THE ESSENTIAL RESEARCH AND THERAPY DEVELOPMENT. AND IT IS THIS BALANCING TEST THAT HAS GUIDED THE AGENCY'S DEVELOPMENT OF ITS IP POLICIES SINCE 2005 AND THEIR PERIODIC CALIBRATIONS SINCE THEN.

BEFORE WE GET TO THE PROPOSED REVISIONS, I JUST WANT TO REMIND YOU OF A FEW OF THE BASIC COMPONENTS AND PRINCIPLES OF OUR CURRENT IP REGULATIONS. FIRST OF ALL, CIRM DOES NOT TAKE AN OWNERSHIP INTEREST IN ANY IP THAT'S CREATED WITH CIRM FUNDING. LIKE THE FEDERAL GOVERNMENT, CIRM BELIEVES THAT OUR AWARDEES ARE MORE INCENTIVIZED TO

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EXPLOIT INTELLECTUAL PROPERTY WHEN THEY OWN THEIR DISCOVERIES. HOWEVER, SECOND, WHILE WE DON'T OWN IP, WE WANT TO MAKE SURE THAT OUR AWARDEES TAKE REASONABLE STEPS TO PUSH IP FORWARD, SO WE MAKE THAT A REQUIREMENT. THIRD, WE DON'T REQUIRE THAT AWARDEES PUBLISH RESULTS OF THEIR RESEARCH; BUT IF THEY DO, WE MAINTAIN A COMMONLY ACCEPTED REQUIREMENT THAT MATERIALS BE MADE AVAILABLE FOR RESEARCH PURPOSES IN CALIFORNIA.

AND THEN, FINALLY, WHILE THE VAST BULK OF RETURN THE STATE WILL BE IN THE FORM OF REDUCED HEALTHCARE COSTS AND INCREASED PRODUCTIVITY RESULTING FROM THERAPIES AND CURES, WE HAVE IMPOSED DIRECT RETURN TO THE STATE THROUGH PRICING AND ACCESS PROVISIONS, AS WELL, OF COURSE, AS THE REVENUE SHARING. AND IT'S THE REVENUE SHARING THAT WE WANT TO FOCUS ON IN THESE REVISIONS.

TO APPRECIATE, HOWEVER, THE CHANGES THAT WE'D LIKE YOU TO CONSIDER TODAY, IT'S IMPORTANT JUST TO HAVE A VERY GENERAL UNDERSTANDING OF THE WAY THE REVENUE SHARING REQUIREMENTS WORK, WHICH ARE COVERED IN THIS AND THE NEXT SLIDE. BY THE WAY, I'M ON SLIDE 5 FOR THOSE WHO HAVE THEIR OWN SLIDE DECK.

WHEN WE TALK ABOUT REVENUE SHARING WITH OUR AWARDEES, WE PRIMARILY TALK ABOUT EITHER OF TWO

TYPES. ONE IS LICENSING REVENUE AND THE SECOND IS COMMERCIAL REVENUE. LICENSING REVENUE IS A CUT THAT THE STATE GETS WHEN OUR AWARDEE LICENSES TECHNOLOGIES TO THIRD PARTIES AND RECEIVES REVENUE DOWNSTREAM FROM THAT THIRD PARTY. IT'S IMPORTANT TO NOTE THAT LICENSING REVENUE IS NEVER COLLECTED FROM THE THIRD PARTY, BUT IS ONLY AN OBLIGATION OF OUR ORIGINAL AWARDEE. HOW MUCH OUR AWARDEE SHARES DEPENDS ON A FORMULA THAT CONSIDERS HOW GREAT CIRM'S INVOLVEMENT WAS DURING THE PROJECT PERIOD OF THE AWARD, AND THE SHARE WILL BE EITHER 15 PERCENT OR 25 PERCENT. HOWEVER, IN PRACTICAL EFFECT, THE ONLY TYPE OF AWARDEE THAT IS SUBJECT TO SHARING LICENSING REVENUES IS A NONPROFIT AWARDEE. FOR-PROFIT AWARDEES ARE TREATED DIFFERENTLY AS YOU WILL SEE NEXT ON SLIDE 6.

SO THE OTHER TYPE OF REVENUE SHARING IS COMMERCIAL REVENUE. IF OUR AWARDEE LICENSES OR SELF-COMMERCIALIZES A SUCCESSFUL PRODUCT, WE IMPOSE A ROYALTY ON NET COMMERCIAL REVENUES ACCORDING TO THE FORMULA DESCRIBED HERE. WHAT IS IMPORTANT TO UNDERSTAND ABOUT NET COMMERCIAL REVENUE IS THAT THIS ONLY APPLIES TO FOR-PROFIT AWARDEES. SO, IN ESSENCE, AND, AGAIN, THIS IS A GENERAL RULE, BUT ONE WAY TO THINK ABOUT OUR RULES IS THAT IF YOU ARE A

NONPROFIT AWARDEE, YOU WILL SHARE LICENSING REVENUES WITH THE STATE. AND IF YOU ARE A FOR-PROFIT AWARDEE, A COMMERCIALIZING ENTITY, YOU WILL OWE A ROYALTY ON COMMERCIAL REVENUES.

SO THAT BRINGS US TO WHAT THE GOALS ARE FOR THIS REVISION PROJECT WHEN WE SAT DOWN PER RANDY'S CHARGE. AS THE CIRM TEAM HAS DONE WITH OTHER POLICIES AND RULES, WE WANT TO ENSURE THAT OUR REVENUE SHARING RULES ARE CLEAR AND SELF-EXECUTING WHERE POSSIBLE. IT SHOULDN'T DEPEND ON WHOM YOU TALK TO TO DETERMINE HOW OUR RULES OPERATE. PART OF MAKING THAT POSSIBLE IS ENSURING THAT THE RULES USE OBJECTIVE INSTEAD OF SUBJECTIVE STANDARDS WHERE POSSIBLE. IN OTHER WORDS, WE SHOULD EXPLICITLY STATE AN EXPECTED OUTCOME AS OPPOSED TO TRYING TO REQUIRE A TYPE OF BEHAVIOR SUCH AS "REASONABLE EFFORTS."

TIME AND TIME AGAIN THROUGHOUT THE DEVELOPMENT OF OUR REVENUE SHARING RULES, WE HEARD CLEARLY FROM INDUSTRY THAT THEY ARE LESS CONCERNED ABOUT THE GIVEN BALANCE POINT OR PARTICULAR ROYALTY RATE SO MUCH AS THEY PRIZE THE PREDICTABILITY OF MAKING THAT CALCULATION IN ADVANCE. REVENUE SHARING RULES SHOULD BE SIMPLE TO CALCULATE PRIOR TO TAKING AN AWARD AND PROVIDE CERTAINTY AND CONFIDENCE IN

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THOSE CALCULATIONS.

FINALLY, WE KNOW WE HAVE A GOOD SYSTEM IN PLACE WHEN CIRM TEAM RESOURCES ARE FOCUSED ON SUPPORTING CIRM'S STRATEGIC MISSION RATHER THAN EXPENDING ITS EFFORTS GRAPPLING WITH INTERPRETATION OF OUR OWN RULES AND TRYING TO ENFORCE THEM ON A CASE-BY-CASE BASE.

AND NOW I'M ON SLIDE 8. SO WHAT HAS OUR EXPERIENCE BEEN? FIRST, THE FUNDAMENTAL PREMISE OF OUR IP REGULATIONS ALL ALONG HAS BEEN THE NOTION THAT THE STATE'S INTERESTS ARE ALIGNED WITH THOSE OF OUR AWARDEES, THAT THEY'LL MAKE THE BEST DEAL AND, IN TURN, THE STATE WILL SHARE IN THAT REWARD. IN PRACTICE, HOWEVER, THIS IS NOT ALWAYS THE CASE, AND IT IS ESPECIALLY TRUE IN LIGHT OF THE FACT THAT SOME GRANTEES DON'T TYPICALLY LICENSE DATA, WHICH IS USUALLY THE TYPE OF IP THAT'S GENERATED IN LATE STAGE CLINICAL AWARDS THAT CIRM FUNDS. WHEN THERE'S NO LICENSE, THERE'S NO LICENSE REVENUE. MOREOVER, A LICENSE CAN BE AVOIDED IF DATA OR OTHER IP IS MADE PUBLICLY AVAILABLE.

FINALLY, EVEN IF THERE IS A LICENSE, THE CURRENT REQUIREMENT ONLY REQUIRES REASONABLE EFFORTS, WHICH CAN LEAD TO DISAGREEMENT OVER WHAT THOSE EFFORTS SHOULD BE. AND BY WAY OF RECENT

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EXAMPLE, WE HAD AN APPLICANT VERY RECENTLY WHO APPLIED FOR A CLIN STAGE AWARD, A SIGNIFICANT AWARD. A REVIEW OF THAT LICENSING AGREEMENT REVEALS THAT A 2.5 PERCENT ROYALTY RATE FOR THE AWARDEE'S UNDERLYING IP HAD BEEN NEGOTIATED. AND IN THE EVENT THAT THE DATA THAT WOULD BE GENERATED BY OUR AWARD WAS ALSO ADDED TO THE DEAL, JUST A QUARTER OF 1 PERCENT WAS ADDED TO THAT OVERALL ROYALTY RATE. AND OUR SHARE, AS YOU KNOW, WOULD BE JUST 15 TO 25 PERCENT OF THAT QUARTER OF 1 PERCENT, WHICH RESULTS IN A VERY SMALL RETURN FOR A LARGE INVESTMENT AT A CRITICAL JUNCTURE OF THE RESEARCH.

SO NOW I'M ON SLIDE 9. WHEN LICENSING REVENUE IS DUE, CALCULATING THAT AMOUNT CAN BE PROBLEMATIC WHEN DETERMINING THE EXTENT OF THIRD-PARTY PARTICIPATION, WHICH CAN ALTER THE AMOUNT THAT'S DUE TO THE STATE. ALSO, AS WE DISCUSSED, THE SCOPE OF PAYMENTS AN AWARDEE RECEIVES THAT MAY BE SUBJECT TO SHARE WITH THE STATE DIFFERS DEPENDING ON THE PROFIT STATUS OF THE AWARDEE, WHICH CAN RESULT IN VASTLY DIFFERENT CALCULATIONS.

FINALLY, APPLYING THE CURRENT RULES TO THE MANY COMPLEX DRUG DEVELOPMENT SCENARIOS CAN LEAD TO REASONABLE DISAGREEMENT, WHICH CREATES UNCERTAINTY REGARDING OUR AWARDEES' OBLIGATIONS. ALSO, BECAUSE

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OF THE COMPLEXITY OF THE CURRENT SYSTEM, SIGNIFICANT ADMINISTRATIVE TIME IS SPENT INTERPRETING, EXPLAINING, AND ENFORCING OUR TERMS. AND BECAUSE INTERPRETATION CAN BE SUBJECTIVE, SUCH AS WHAT IT MEANS TO USE REASONABLE EFFORTS TO LICENSE, THE RULES CAN BE DIFFICULT FOR AWARDEES TO PENCIL OUT PRIOR TO ACCEPTING AN AWARD. INDEED, THE EFFORT OF COMPLIANCE ITSELF CAN CAUSE DELAYS IN GETTING PROJECTS MOVING FORWARD.

AND, FINALLY, AS WE DISCUSSED, OUR CURRENT SCHEME TREATS FOR-PROFITS AND NON-PROFITS DIFFERENTLY. WHEN THE CONCEPT OF COMMERCIAL REVENUE SHARING WAS FIRST ADOPTED A FEW YEARS AGO, THERE WAS NATURALLY SOME UNCERTAINTY AS TO HOW THE SYSTEM WOULD BE RECEIVED BY THE FOR-PROFIT SECTOR AND ITS IMPACT ON DEVELOPING OUR AWARDS. BUT BASED ON THE LAST FEW YEARS' EXPERIENCE, THE FOR-PROFIT SECTOR HAS LARGELY EMBRACED THIS CONCEPT, AND IT DOES NOT APPEAR TO BE A SIGNIFICANT IMPEDIMENT TO COMMERCIAL PARTICIPATION IN OUR AWARD PROGRAM. THUS, WE FEEL THAT THE TIME IS RIGHT TO TREAT AWARDEES UNIFORMLY.

TO ILLUSTRATE THE EFFECT OF OUR CURRENT SCHEME, THE EXAMPLE ON THE SLIDE SHOWS THE DIFFERENCE TO THE STATE IF PHARMA LICENSES CIRM TECHNOLOGIES FROM A FOR-PROFIT OR A NOT-FOR-PROFIT.

THE UPSIDE TO THE STATE IN HARMONIZING OUR RULES MAY BE SIGNIFICANT.

SO WITH THOSE CHALLENGES, AND I'M ON SLIDE 12 NOW, THE CIRM TEAM IS PROPOSING THAT WE 2.0 OUR REGULATIONS. SO IN ADDITION TO REFINING REPORTING AND OTHER REQUIREMENTS, WE PRIMARILY PROPOSE THE FOLLOWING REVISIONS. FIRST, WE WANT TO ELIMINATE THE DISPARATE TREATMENT OF AWARDEES AND TREAT ALL AWARDEES ALIKE REGARDLESS OF THEIR PROFIT STATUS.

SECOND, WE WANT TO ELIMINATE THE CONCEPT OF LICENSING REVENUE FOR ALL AWARDEES AND FOCUS INSTEAD ON THE COMMERCIAL REVENUE CONCEPT THAT IS CURRENTLY APPLICABLE ONLY TO FOR-PROFIT AWARDEES.

WHILE THESE CHANGES ARE SIGNIFICANT, IN DOING SO, WE INTEND TO MAKE NO SUBSTANTIVE CHANGES TO OUR CURRENT ACCESS AND PRICING PROVISIONS. BY ELIMINATING LICENSING REVENUE AND FOCUSING ON COMMERCIAL SUCCESSES, WE BELIEVE WE CAN OPTIMIZE CIRM'S REMAINING RESOURCES WHICH WILL ALLOW US TO FOCUS ON CIRM'S STRATEGIC MISSION. BY SIMPLIFYING OUR REVENUE SHARING RULES, WE WILL MAKE THEM EASIER TO UNDERSTAND, EXPLAIN, AND ADMINISTER. AND AS A RESULT, POTENTIAL APPLICANTS WILL BE ABLE TO MORE ACCURATELY PREDICT THE COST OF CIRM'S MONEY AND, THUS, LIKELY MAKE CIRM'S PROGRAMS MORE ATTRACTIVE TO

FOLLOW-ON INVESTMENT AND COMMERCIALIZATION.

AND SO WITH THAT, I WILL TOSS IT BACK TO STEVE AND JUST LET THE GROUP KNOW THAT BEN AND JAMES AND I ARE HERE TO ANSWER YOUR QUESTIONS ABOUT NOT ONLY THIS PROPOSAL, BUT ALSO THE PROCESS MOVING FORWARD. STEVE.

CHAIRMAN JUELSGAARD: YES. THANK YOU SCOTT. THANK YOU FOR THAT VERY COMPREHENSIVE REVIEW.

WHAT I'D LIKE TO DO IS OPEN THIS UP TO QUESTIONS, BUT I HAVE ONE PREDICATE CLARIFICATION JUST SO EVERYBODY UNDERSTANDS. TO WHICH AWARDS DOES THIS PROPOSED CHANGE APPLY?

MR. TOCHER: THESE CHANGES, ONCE THEY TAKE EFFECT, WILL APPLY ONLY TO AWARDS MADE AFTER THE EFFECTIVE DATE OF THE REGULATIONS, WHICH IS AFTER THE PROCESS WITH OAL IS COMPLETED. THAT SAID, WE HAVE WRITTEN A PROVISION THAT WOULD ALLOW EXISTING AWARDEES TO, IN ESSENCE, ADOPT THIS NEW SCHEME IF THEY CHOOSE TO DO SO WITH CIRM'S AGREEMENT.

CHAIRMAN JUELSGAARD: THANK YOU. JUST ONE QUICK FOLLOW-UP QUESTION TO THAT, AND THEN I WILL LET OTHERS ASK QUESTIONS. WHEN THEY'RE FINISHED, I HAVE A FEW MORE. BUT JUST TO FOLLOW UP ON THAT, IMAGINE THAT SOMEBODY HAS AN EXISTING GRANT AT THIS

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POINT AND SO IS SUBJECT TO THE REGULATIONS THAT STAND NOW. LET'S SAY A YEAR FROM NOW, LET'S ASSUME WE GO AHEAD AND ADOPT THESE REGULATIONS AT THE ICOC, SO WE HAVE NOW NEW REGULATIONS. SO A YEAR FROM NOW THEY COME IN AND THEY APPLY FOR ANOTHER GRANT IN THE CONTINUUM OF DEVELOPING A PRODUCT THAT IS MOVING FROM ONE STAGE TO ANOTHER. IN THAT CASE, HOW DO THE REGULATIONS APPLY?

MR. TOCHER: THAT'S A GREAT QUESTION, STEVE, AND ONE THAT WE'VE THOUGHT ABOUT FOR SOME TIME NOW. SO WHAT WE'VE DONE IS WE'VE INCLUDED A NEW PROVISION, 612, WHICH IS AT THE LAST REGULATION, AND WHAT THAT STATES IS THAT WHEN YOU HAVE A CONTINUUM OF INVESTMENT, THE MOST RECENT ITERATION OF THE RULES WOULD APPLY.

CHAIRMAN JUELSGAARD: ALL RIGHT. ESSENTIALLY, THEN, AS I UNDERSTAND IT, IF THEY APPLY FOR AND RECEIVE A GRANT POSTADOPTION OF THESE REGULATIONS, THESE REGULATIONS WILL SUPERSEDE WHAT CAME BEFORE?

MR. TOCHER: THAT'S RIGHT.

CHAIRMAN JUELSGAARD: THANK YOU. ALL RIGHT. SO QUESTIONS ANYONE? OR COMMENTS?

MR. PANETTA: STEVE, THIS IS JOE. I'VE GOT A COUPLE OF QUESTIONS.

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CHAIRMAN JUELSGAARD: GO AHEAD.

MR. PANETTA: FIRST, I JUST WANTED TO KNOW IF WE'VE COLLECTED ANY LICENSING ROYALTY REVENUE TO DATE? I KNOW ON THE COMMERCIAL SIDE WE HAVEN'T, BUT I JUST WAS WONDERING ON THE NONCOMMERCIAL. IS ANY LICENSING -- UNDER THIS SCHEME HAS ANY REVENUE BEEN COLLECTED BY THE STATE?

MR. TOCHER: NOT YET. THE STATE HAS NOT RECEIVED ANY FUNDS. HOWEVER, WE DO HAVE ONE AWARDEE THAT IS POISED TO RETURN SOME FUNDS TO THE STATE. BEN HUANG IS HERE AND HAS A LITTLE MORE DETAIL ON THAT IF YOU'D LIKE.

MR. HUANG: WE AT LEAST HAVE ONE LICENSE AGREEMENT THAT HAS QUALIFIED FOR PAYMENT OF FUNDS TO THE STATE.

I THINK WHAT SCOTT SAID PREVIOUSLY ABOUT BUREAUCRATIC ISSUES, I'VE BEEN DEALING WITH THEM FOR APPROXIMATELY SEVEN OR EIGHT MONTHS TO TRY TO GET THEM TO DEVISE A FORMULA FOR THAT PAYMENT. AND I MAY HAVE TO MEET WITH THEM IN PERSON. IT'S BEEN DIFFICULT.

MR. PANETTA: THANKS. AND THEN MY OTHER QUESTION IS, AS YOU THOUGHT ABOUT THIS, IS ONE OF THE KEY FACTORS THAT'S DRIVING THIS THE EXPECTATION THAT REVENUE SHARE IN THE FUTURE WILL LARGELY COME

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THROUGH COMMERCIAL CHANNELS ON THE PHARMA SIDE BARRING THESE TECHNOLOGIES? IS THAT PART OF THE THINKING?

MR. TOCHER: I THINK THAT'S RIGHT. YES, JOE.

MR. PANETTA: OKAY. ALL RIGHT. THANKS.

CHAIRMAN JUELSGAARD: ALL RIGHT. SO OTHER QUESTIONS FROM OTHER COMMITTEE MEMBERS?

CHAIRMAN THOMAS: STEVE, I'VE GOT A QUESTION.

SCOTT, YOU SAID THAT THE OUTSTANDING GRANTEES MAY CHOOSE TO ADOPT THESE NEW REGS IF THEY WANT TO. WHAT'S THE INCENTIVE FOR THEM TO DO THAT? AND TO THE EXTENT THAT WE WOULD FIND THAT A FAVORABLE DEVELOPMENT, HOW CAN WE INCENTIVIZE THEM TO DO THAT?

MR. TOCHER: WELL, IF OUR THEORY IS RIGHT, THAT A SIMPLER AND EASIER, MORE STREAMLINED VERSION OF THE REGULATIONS IS TO EVERYONE'S BENEFIT, THEN WE THINK THAT THE INCENTIVE WILL LIE THERE. AND IN TERMS OF OUTREACH, OF COURSE, WE ALWAYS MAKE, OUR NEW POLICIES AND SUCH, OUR AWARDEES AWARE OF IT. I THINK THE INCENTIVE ON THEIR SIDE WILL BE JUST AS WE'VE DESCRIBED IT, IN WHICH CASE IT'S DIFFICULT TO FORESEE A CIRCUMSTANCE WHERE WE WOULDN'T AGREE TO

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APPLY THOSE RETROACTIVELY.

MR. HUANG: J.T., I THINK ONE OF THE INCENTIVES FOR THE NONPROFIT INSTITUTIONS IS THAT THEY NO LONGER WOULD HAVE TO PAY OUT OF THEIR LICENSING REVENUE AND WOULD JUST INSERT A ROYALTY INTO A LICENSE AGREEMENT WITH THE POTENTIAL COMMERCIALIZING ENTITY. SO THEY'LL HAVE TO WEIGH THE KIND OF -- THEY'LL HAVE TO DO THE FINANCIAL CALCULATIONS THERE ABOUT WHETHER TO ADOPT.

CHAIRMAN JUELSGAARD: ARE THERE OTHER QUESTIONS? ALL RIGHT. WELL, THEN, IF NOT, I'LL COME BACK AROUND AGAIN. I JUST HAVE A COUPLE.

SO I'D LIKE TO FOCUS, SCOTT AND BEN, ON THE TERM "REGULATORY USE," WHICH IS GG UNDER THE DEFINITIONS. AND IT TALKS ABOUT THE USE OF RESEARCH IN A SUBMISSION OR FILING WITH THE FDA OR A SIMILAR BODY. SO I THINK WE SHOULD SIMPLY POINT OUT THAT NOT ALL USES OF CIRM MONEY IN TERMS OF RESEARCH WOULD BE SWEPT IN UNDER THE TERM "REGULATORY USE." SO OFTENTIMES IN EARLY RESEARCH THIS CAN BE CERTAINLY PRETRANSLATIONAL; BUT ALSO DURING THE TRANSLATIONAL PERIOD, EFFORTS ARE MADE IN TERMS OF DOING BASIC RESEARCH TO TRY AND IDENTIFY POTENTIAL TRANSLATIONAL PRODUCT, AND THEN DURING THE TRANSLATIONAL PERIOD TO MORE HONE IN. AND THAT

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WORK, THAT EFFORT, THAT DATA WILL NOT FIND ITS WAY NECESSARILY INTO THE FDA FILING.

SO I THINK IT'S FAIR TO POINT OUT THAT, BY USING THIS, AND I THINK THIS IS A MUCH CLEARER WAY OF DOING THINGS -- DON'T GET ME WRONG. I'M NOT SUGGESTING WE SHOULD NOT GO DOWN THIS ROAD -- BUT I THINK IT'S IMPORTANT TO UNDERSTAND THAT THERE WILL BE CIRM-FUNDED RESEARCH POTENTIALLY THAT WOULD NOT LEAD TO INFORMATION INCLUDED IN A REGULATORY FILING.

SO I DON'T KNOW IF OTHERS SEE IT DIFFERENTLY. I KNOW, ANNE-MARIE, YOU'VE PROBABLY HAD EXPERIENCE IN THIS REGARD AND OTHERS MAY AS WELL. SO PLEASE COMMENT.

DR. DULIEGE: I CAN'T RECALL IF I HAD EXACTLY SOME RELEVANT EXPERIENCE FROM AN IP PERSPECTIVE AND THE REGULATORY ACTUALLY, NO.

CHAIRMAN JUELSGAARD: OKAY. BASED ON MY EXPERIENCE WITH WHAT GOES ON IN RESEARCH AND ALSO WHEN YOU'RE ULTIMATELY WORKING TOWARDS A MOLECULE, THAT THE FILING CALLS FOR CERTAIN SPECIFIC INFORMATION. IT DOESN'T CALL FOR EVERY PIECE OF INFORMATION EVER GENERATED LEADING UP TO SUCH-AND-SUCH BEING CONSIDERED FOR EITHER AN IND OR A PREQUEL. AND ONE OF THE THINGS, AND THIS IS JUST PART OF WHAT GOES ON, IS SOMETIMES YOU GENERATE

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INFORMATION, YOU SPEND MONEY, YOU GENERATE INFORMATION THAT ACTUALLY POINTS YOU IN A VERY DIFFERENT DIRECTION. IN OTHER WORDS, NEGATIVE RESULTS CAN BE AS IMPORTANT AS POSITIVE RESULTS. THEY THEN TURN YOU AWAY FROM A DIRECTION THAT YOU WERE HEADED AND INTO A NEW DIRECTION WHICH TURNS OUT TO BE SUCCESSFUL.

SO, ANYWAY, I'M NOT SUGGESTING AT ALL THAT WE CHANGE THIS. I'M JUST POINTING OUT THAT SOME OF OUR FUNDING MAY NOT OTHERWISE MAKE IT INTO A REGULATORY FILING.

THE OTHER QUESTION RELATES TO THE TERM "DRUG," WHICH IS UNDER DEFINITIONS J. AND I WANTED TO FOCUS AT THE END OF THAT DEFINITION. OBVIOUSLY THIS IS OLD LANGUAGE, NOT NEW LANGUAGE, AND IT'S ONE OF THE VIRTUES AND VICISSITUDES OF DOING THIS IS THAT YOU TEND TO LOOK AT EVERYTHING WITH NEW EYES. THIS TERM INCLUDES THERAPEUTIC PRODUCTS SUCH AS BLOOD, BLOOD PRODUCTS, AND CELLS, BUT EXCLUDES MEDICAL PROCEDURES AND SERVICES RELATING THERETO.

I WANT TO FOCUS ON THE EXCLUSION OF THE MEDICAL PROCEDURES AND SERVICES RELATING THERETO, PARTICULARLY IN THE AREA WHERE WE HAVE NO INDIVIDUALIZED TREATMENT OF PATIENTS. SO THAT IT MAY WELL BE THAT USE OF CIRM FUNDS IN THE

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DEVELOPMENT OF A PARTICULAR TREATMENT GO BOTH TO A SUBSTANCE AS WELL AS TO BOTH EXTRACT AND REINTRODUCE THAT SUBSTANCE FROM THE BODY, PARTICULAR PROCEDURES THAT ARE PAID FOR AS PART OF THE CIRM FUNDING AND BECOME PART OF THE PRACTICE IN TERMS OF DOING THIS PRACTICE OR PROCEDURE.

AND THE SECOND PART OF IT IS I DON'T KNOW HOW -- I'M SURE OTHERS HAVE MORE EXPERIENCE THAN I'VE HAD, BUT HOW DOES ONE SORT OUT OR SEGREGATE THE VALUE OF THE CELLS OR BLOOD PRODUCTS OR BLOOD FROM THE PROCEDURE ITSELF AND THE MECHANICAL PARTS OF THE PROCEDURE? I MEAN WHAT THE VALUE COMPONENT OF EACH IS. SO I'M JUST CURIOUS AS TO HOW WE THOUGHT ABOUT THOSE THINGS.

MR. HUANG: AND I WILL ADDRESS YOUR FIRST QUESTION ABOUT WHERE YOU POINTED OUT THERE'S POTENTIALLY DATA THAT MAY NOT BE COVERED BY REGULATORY USE. I THINK WITH REGARDS TO BASIC RESEARCH, IN OUR COMMERCIALIZING CLAUSE WE ALSO, BESIDES REGULATORY USE, ALSO COVER ANY LICENSE AGREEMENTS WITH REGARDS TO CIRM-FUNDED INVENTIONS. SO THAT'S ADDITIONAL COVERAGE WITH REGARDS TO COVERING THE BASIC RESEARCH SIDE.

AND THEN ON THE NONDRUG SIDE, WE ALSO HAVE THE COMMERCIALIZING ENTITY WOULD PAY ROYALTY ON

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NONDRUGS THAT HAVE LICENSE AGREEMENTS RELATING TO CIRM-FUNDED INVENTIONS. SO WE RECOGNIZE THAT THERE COULD BE BASIC RESEARCH THAT IS LIKE A BLOCKBUSTER THAT DOES NOT ACTUALLY DEAL WITH A THERAPY AND HOPE TO CAPTURE THAT. AND THEN RECOGNIZE THAT THE DEFINITION WILL NOT COVER CERTAIN ASPECTS OF BASIC RESEARCH THAT DO NOT FALL INTO THESE KIND OF THREE BUCKETS THAT WE HAVE. BUT WE'RE WILLING, OBVIOUSLY, TO ENTERTAIN CHANGES TO THAT STRUCTURE, BUT WE TRIED TO CAPTURE AS MUCH AS WE COULD IN A SIMPLE FASHION.

SO IT WOULD BE REGULATORY USE. OTHERWISE IT WOULD BE INVENTIONS THAT ARE COVERED BY LICENSE AGREEMENTS, CIRM-FUNDED INVENTIONS COVERED BY LICENSE AGREEMENTS.

CHAIRMAN JUELSGAARD: I UNDERSTAND THAT, BEN, AND I APPRECIATE THAT. AND MY POINT IS NOT TO MAKE THE THING MORE COMPLICATED THAN IT ALREADY IS. YOUR EFFORTS TO SIMPLIFY THIS I VERY MUCH APPRECIATE AND APPLAUD. I JUST SIMPLY WANTED TO MAKE THE POINT, JUST SO THERE WAS CLARITY, THAT THERE'S LIKELY TO BE THINGS THAT WE FUND THAT IN THE END LEAD TO SUCCESSFUL OUTCOME, BUT WE MAY NOT SEE A RETURN ON IT SIMPLY BECAUSE OF THE NATURE OF THE BEAST. SO I'M NOT PROPOSING THAT WE ADD ANY OTHER LANGUAGE OR CHANGE ANY LANGUAGE OR WHATEVER, JUST

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SIMPLY THAT PEOPLE DON'T GET THE IMPRESSION THAT THIS IS BULLETPROOF AND EVERYTHING THAT CIRM FUNDS RESULTS IN A STEP FORWARD IN SOME FASHION WILL RESULT IN A RETURN OF REVENUE TO THE STATE BECAUSE IT'S REALLY DIFFICULT TO MAKE THAT HOLD IN EVERY INSTANCE.

WHAT WAS THE SECOND POINT THEN?

MR. HUANG: AND THEN I THINK WITH REGARDS TO YOUR SECOND QUESTION, I WILL TAKE A FIRST SHOT AT IT AND THEN SEE IF MY COLLEAGUES CAN ADD ON.

I THINK THE WAY I LOOK AT MEDICAL PROCEDURES AND SERVICES AND HOW CIRM HAS BEEN FUNDING PROJECTS, WE'RE NOT FUNDING THOSE IN ISOLATION. SO WITH REGARDS TO -- I THINK YOUR QUESTION ABOUT HOW DO YOU VALUE POTENTIALLY THE SEPARATE COMPONENTS, IT WOULDN'T MATTER UNDER OUR ROYALTY PARADIGM BECAUSE OUR ROYALTY WOULD JUST APPLY. AND IT WOULD BE -- AND THE ROYALTY IS STRUCTURED UPON THE GRANT SIZE. I THINK THAT'S THE KIND OF A QUESTION THAT WE HAVE SET UP SO THAT WE DON'T NEED TO ADDRESS KIND OF THE PARSING OF MEDICAL DEVICE PROCEDURE SEPARATE FROM POTENTIALLY THE DRUG ITSELF.

CHAIRMAN JUELSGAARD: SO I'M PROBABLY NOT BEING CLEAR ENOUGH. SO IMAGINE, FOR EXAMPLE, THAT

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WE HAVE A TREATMENT THAT'S INDIVIDUALIZED. SO IT'S SPECIFIC TO AN INDIVIDUAL. SO CELLS ARE WITHDRAWN FROM THAT INDIVIDUAL, THEY'RE MODIFIED IN SOME FASHION, AND REINTRODUCED INTO THAT INDIVIDUAL. SO WE HAVE A COMBINATION OF INDIVIDUALIZED CELLS BEING WITHDRAWN UNDERGOING SOME SORT OF MODIFICATION, BEING REINTRODUCED, AND THERE ARE ASPECTS OF THAT THAT RELATE TO THE CELL AND ASPECTS OF THAT THAT RELATE TO THE MEDICAL PROCEDURE. AND WHEN THE CHARGE COMES FOR THAT, WHEN THE PRICE FOR THAT COMES, ASSUME, LET'S JUST SAY, AND THIS IS GOING TO BE EXPENSIVE, BUT LET'S SAY IT'S $100,000 FOR THE SAKE OF A DISCUSSION. THAT'S THE CHARGE THE INSURANCE COMPANY -- TO THE PATIENT, TO THE INSURANCE COMPANY, ETC. I'M IMAGINING IT ISN'T BROKEN OUT BY, WELL, WE CHARGE THIS MUCH FOR THE CELLS AND WE MODIFIED THIS MUCH FOR THE PROCEDURES AND SERVICES, BUT RATHER IT'S THOUGHT OF AS A UNITARY WHOLE.

IF I'M MISTAKEN, IF THAT'S NOT HOW THESE THINGS WORK, THEY'RE ACTUALLY BROKEN OUT, AND THE VALUE OF EXTRACTING AND MODIFYING, IF THE VALUE OF THE CELLS THEMSELVES CAN BE DETERMINED IN THAT EXAMPLE, WHICH I THINK MIGHT BE DIFFICULT, BUT NONETHELESS, REMEMBER WE'RE INCORPORATING THE TERM

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"MEDICAL SERVICE," SO IS THE MODIFICATION OF THE CELLS A PART OF A SERVICE VERSUS THE CELLS THEMSELVES? IT'S THOSE KIND OF INSTANCES THAT I'M WONDERING ABOUT IN THIS DEFINITION.

MR. HARRISON: STEVE, I THINK THOSE ARE GOOD QUESTIONS AND SOMETHING WE NEED TO TAKE A CLOSER LOOK AT. AS YOU OBSERVE, WE HADN'T, WITH RESPECT TO OUR CHANGES, FOCUSED ON THAT PART OF THE DEFINITION. BUT IN LIGHT OF THESE PROPOSED REVISIONS, WE'LL TAKE A CLOSER LOOK AT THE DEFINITION AND MAKE SURE IT IS CONSISTENT AND ACTUALLY OPERATIONALIZED.

CHAIRMAN JUELSGAARD: THANK YOU, JAMES. I'M NOT TRYING TO INCREASE THE WORKLOAD HERE. I REALIZE THIS IS NOT IN THE BOUNDARIES OF WHAT YOU GUYS WERE LOOKING AT. BUT, LIKE I SAID, ONE OF THE VICISSITUDES, PERHAPS, OF THIS WHOLE PRACTICE IS YOU GO BACK AND READ EVERYTHING AGAIN AND PICK UP THINGS YOU MAY NOT HAVE SEEN THE FIRST TIME.

MR. HARRISON: ABSOLUTELY. WE, BY THE WAY, WELCOME THOSE SUGGESTIONS. I KNOW THE THREE OF US HAVE SPENT A LOT OF TIME REVIEWING THE EXISTING IP REGS OVER AND OVER AGAIN. I WILL SAY EACH TIME WE REVIEW WE IDENTIFY SOME OTHER ISSUE OR DEFINITION THAT CAUSES US TO SCRATCH OUR HEADS AND ASK WHY IS

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IT WRITTEN THAT WAY. SO WE WELCOME ANY SUGGESTIONS YOU HAVE WITH RESPECT TO THE CHANGES OR THE EXISTING LANGUAGE.

CHAIRMAN JUELSGAARD: THANK YOU. ALL RIGHT. SO I'M GOING TO -- BEFORE I ASK FOR PUBLIC QUESTION OR COMMENT, I WANT TO GO AROUND THE COMMITTEE MEMBERSHIP ONE MORE TIME AND SEE IF THERE ARE ANY OTHER QUESTIONS OR COMMENTS.

DR. DULIEGE: I REALLY APPRECIATED THE DISCUSSION. I CAN'T CONTRIBUTE TO THE DETAILS OF THE IP PART OF IT, BUT I CERTAINLY CAN UNDERSTAND THE ESSENCE OF WHAT WE INTEND TO DO, AND I REALLY THINK IT'S VERY VALUABLE.

CHAIRMAN JUELSGAARD: THANK YOU, ANNE-MARIE. ANY OTHERS? IF NOT, THEN, DO WE HAVE ANY QUESTIONS OR COMMENTS FROM ANY MEMBER OF THE PUBLIC?

MR. HARRISON: DOESN'T APPEAR SO, STEVE.

CHAIRMAN JUELSGAARD: ALL RIGHT. IF THERE ARE THEN NO OTHER QUESTIONS AND COMMENTS FROM THE COMMITTEE OR SUBCOMMITTEE OR FROM THE PUBLIC, I ASSUME THIS IS THE ONLY TOPIC, SCOTT, THAT WE'RE GOING TO COVER, RIGHT?

MR. TOCHER: THAT'S CORRECT, STEVE.

CHAIRMAN JUELSGAARD: THEN THE MEETING IS

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ADJOURNED.

MR. TOCHER: STEVE, IF I COULD JUST ASK THE COMMITTEE THAT WE HAVE A MOTION TO RECOMMEND.

CHAIRMAN JUELSGAARD: EXACTLY. SORRY, SCOTT. GOOD POINT. IS THERE A MOTION TO RECOMMEND THESE CHANGES TO THE ICOC?

CHAIRMAN THOMAS: SO MOVED.

CHAIRMAN JUELSGAARD: MOVED BY J.T. SECOND?

DR. DULIEGE: I SECOND.

CHAIRMAN JUELSGAARD: ANNE-MARIE SECONDS. DO YOU WANT TO DO THE ROLL, MARIA.

MS. BONNEVILLE: SURE.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: STEVE JUELSGAARD.

CHAIRMAN JUELSGAARD: YES.

MS. BONNEVILLE: JOE PANETTA.

MR. PANETTA: YES.

MS. BONNEVILLE: JEFF SHEEHY. OS STEWARD. JONATHAN THOMAS.

CHAIRMAN THOMAS: YES.

MS. BONNEVILLE: MOTION CARRIES.

CHAIRMAN JUELSGAARD: ALL RIGHT. NOW I'M GOING TO TURN BACK IS THERE ANYTHING ELSE BEFORE WE

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ADJOURN THE MEETING? ALL RIGHT. THE MEETING STANDS ADJOURNED. THANK YOU.

(THE FOLLOWING WAS THEN HEARD AFTER THE MEETING OFFICIALLY ADJOURNED:)

DR. STEWARD: HEY, MARIA, YOU STILL HERE?

MS. BONNEVILLE: I AM.

DR. STEWARD: I GOT DROPPED THERE AT THE LAST MINUTE. I TAKE IT THERE WAS NOT A VOTE, BUT --

MS. BONNEVILLE: THERE WAS A VOTE. WOULD YOU LIKE US TO GIVE YOU THE MOTION?

DR. STEWARD: SURE.

MR. TOCHER: IT WAS TO RECOMMEND TO THE BOARD APPROVAL OF THE PROPOSED CHANGES.

DR. STEWARD: YES. YES ON THAT. AND I APOLOGIZE. IT WAS WHEN ANNE-MARIE FINISHED, SOMETHING HAPPENED AND I JUST DROPPED OFF ENTIRELY. DON'T KNOW WHAT HAPPENED.

MS. BONNEVILLE: THANK YOU, OS.

(THE MEETING WAS THEN CONCLUDED AT 10:38 A.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 JANUARY 26, 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.

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