

BEFORE THE  
INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE AND THE  
APPLICATION REVIEW SUBCOMMITTEE  
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: AUGUST 25, 2016  
11 A.M.

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

BRS FILE NO.: 98837

BARRISTERS' REPORTING SERVICE

I N D E X

ITEM DESCRIPTION	PAGE NO.
OPEN SESSION	
1. CALL TO ORDER	3
2. ROLL CALL	3
3. CONSIDERATION OF APPLICATIONS SUBMITTED IN RESPONSE TO CLIN 1: PARTNERING OPPORTUNITY FOR LATE STAGE PRECLINICAL PROJECTS AND CLIN 2: PARTNERING OPPORTUNITY FOR CLINICAL TRIAL STAGE PROJECTS.	4
CLOSED SESSION	10
4. DISCUSSION OF CONFIDENTIAL INTELLECTUAL PROPERTY OR WORK PRODUCT, PREPUBLICATION DATA, FINANCIAL INFORMATION, CONFIDENTIAL SCIENTIFIC RESEARCH OR DATA, AND OTHER PROPRIETARY INFORMATION RELATING TO APPLICATIONS CLIN 1: PARTNERING OPPORTUNITY FOR LATE STAGE PRECLINICAL PROJECTS AND CLIN 2: PARTNERING OPPORTUNITY FOR CLINICAL TRIAL STAGE PROJECTS, (HEALTH & SAFETY CODE 125290.30(F)(3)(B) AND (C)).	
5. PUBLIC COMMENT	23
6. ADJOURNMENT	35

BARRISTERS' REPORTING SERVICE

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THURSDAY, AUGUST 25, 2016; 11 A.M.

CHAIRMAN THOMAS: GOOD MORNING, EVERYBODY.  
THIS IS J.T. WELCOME TO THE AUGUST REGULAR MEETING  
OF THE ICOC AND APPLICATION REVIEW SUBCOMMITTEE.  
MARIA, WILL YOU PLEASE TAKE THE ROLL.

MS. BONNEVILLE: DAVID BRENNER. LARS  
BERGLUND. ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: HOWARD FEDEROFF.  
ELIZABETH FINI. MICHAEL FRIEDMAN. JUDY GASSON.  
SAM HAWGOOD. DAVID HIGGINS.

DR. HIGGINS: HERE.

MS. BONNEVILLE: STEVE JUELSGAARD.

DR. JUELSGAARD: PRESENT.

MS. BONNEVILLE: SHERRY LANSING. KATHY  
LAPORTE.

MS. LAPORTE: HERE.

MS. BONNEVILLE: BERT LUBIN. SHLOMO  
MELMED.

DR. MELMED: HERE.

MS. BONNEVILLE: LAUREN MILLER.

MS. MILLER: HERE.

MS. BONNEVILLE: LLOYD MINER. ADRIANA  
PADILLA.

BARRISTERS' REPORTING SERVICE

1 DR. PADILLA: HERE.  
2 MS. BONNEVILLE: JOE PANETTA.  
3 MR. PANETTA: HERE.  
4 MS. BONNEVILLE: FRANCISCO PRIETO.  
5 DR. PRIETO: HERE.  
6 MS. BONNEVILLE: ROBERT QUINT.  
7 DR. QUINT: HERE.  
8 MS. BONNEVILLE: AL ROWLETT. JEFF SHEEHY.  
9 MR. SHEEHY: HERE.  
10 MS. BONNEVILLE: OS STEWARD.  
11 DR. STEWARD: HERE.  
12 MS. BONNEVILLE: JONATHAN THOMAS.  
13 CHAIRMAN THOMAS: HERE.  
14 MS. BONNEVILLE: ART TORRES.  
15 MR. TORRES: HERE.  
16 MS. BONNEVILLE: KRISTINA VUORI. DIANE  
17 WINOKUR. AL ROWLETT.  
18 THANK YOU.  
19 CHAIRMAN THOMAS: OKAY. AS THIS IS THE  
20 MEETING OF THE APPLICATION REVIEW SUBCOMMITTEE, I'M  
21 GOING TO NOW TURN THE MEETING OVER TO MR. SHEEHY.  
22 MR. SHEEHY: THANK YOU, CHAIRMAN THOMAS.  
23 SO I THINK DR. SAMBRANO WILL DO THE INTRODUCTION.  
24 DR. SAMBRANO: THANK YOU, MR. SHEEHY. SO  
25 TODAY WE'RE BRINGING FOR YOUR CONSIDERATION

BARRISTERS' REPORTING SERVICE

1 APPLICATIONS THAT WERE REVIEWED BY THE GRANTS  
2 WORKING GROUP UNDER THE CLINICAL PROGRAM. THERE ARE  
3 FIVE SLIDES THAT I HAVE. THEY'RE NOT NECESSARILY  
4 FOR YOU TO SEE THEM TO FOLLOW ALONG; BUT IF YOU HAVE  
5 ACCESS TO THEM, WHICH THEY ARE AVAILABLE ONLINE, I  
6 WILL TELL YOU WHICH SLIDE I'M ON. SO I'M ON SLIDE  
7 2, WHICH IS JUST SHOWING THE DIFFERENT PROGRAM  
8 ANNOUNCEMENTS THAT RELATE TO THE OVERALL CLINICAL  
9 PROGRAM.

10 WE HAVE ONE APPLICATION TO CONSIDER TODAY  
11 THAT WAS SUBMITTED UNDER THE CLIN2 PROGRAM THAT IS A  
12 CLINICAL TRIAL PROPOSAL.

13 ON THE NEXT SLIDE IS A REMINDER OF THE  
14 SCORING SYSTEM THAT WE UTILIZE FOR APPLICATIONS  
15 UNDER THE CLINICAL PROGRAM. THEY ARE SCORED AS A 1,  
16 2, OR 3. A SCORE OF 1 MEANS THAT THE APPLICATION  
17 HAS EXCEPTIONAL MERIT AND ARE WARRANTS FUNDING. A  
18 SCORE OF 2 MEANS IT NEEDS IMPROVEMENT AND DOESN'T  
19 WARRANT FUNDING AT THIS TIME, BUT COULD BE  
20 RESUBMITTED TO ADDRESS THOSE AREAS FOR IMPROVEMENT.  
21 AND A SCORE OF 3 MEANS THAT IT'S SUFFICIENTLY FLAWED  
22 THAT ITS DOESN'T WARRANT FUNDING AND THAT THE SAME  
23 PROJECT SHOULD NOT BE RESUBMITTED FOR AT LEAST SIX  
24 MONTHS.

25 NOW, BECAUSE THIS IS PERTINENT IN THIS

BARRISTERS' REPORTING SERVICE

1 PARTICULAR CASE, THE SCORE OF 3 REQUIRES A MAJORITY  
2 BY THE GRANTS WORKING GROUP SCIENTIFIC MEMBERS WHO  
3 SCORE IN ORDER FOR AN APPLICATION TO HAVE A SCORE OF  
4 3. WHEREAS, FOR A SCORE OF 1 OR 2, IT REQUIRES A  
5 PLURALITY IN ORDER TO HAVE EITHER THE SCORE OF 1 OR  
6 A 2. IN A CASE WHERE THERE IS NO PLURALITY ACHIEVED  
7 OR WHERE THERE IS NO MAJORITY, THEN IT IS UP TO A  
8 MOTION BY THE GRANTS WORKING GROUP MEMBERS, ALL  
9 MEMBERS, PATIENT ADVOCATES AND SCIENTISTS, AND THEN  
10 A VOTE TO PLACE IT IN ONE OF THOSE THREE TIERS.

11 OKAY. SO THE NEXT SLIDE PRESENTS THE  
12 APPLICATION THAT IS UNDER CONSIDERATION. THIS IS  
13 CLIN2-08839, WHICH IS FOR A CLINICAL TRIAL OF NEW  
14 DEVICE CONFIGURATIONS FOR A THERAPY BEING DEVELOPED  
15 FOR TREATING TYPE 1 DIABETES. SO THE THERAPY ITSELF  
16 IS A COMBINATION OF AN ENCAPSULATION DEVICE THAT  
17 HOLDS WITHIN IT HUMAN EMBRYONIC STEM CELL-DERIVED  
18 PANCREATIC PROGENITOR CELLS THAT MATURE WITHIN THE  
19 DEVICE IN ORDER TO BE EFFECTIVE.

20 AND THE GOAL OF THIS PARTICULAR TRIAL IS  
21 TO TEST DIFFERENT CONFIGURATIONS OF AN EMPTY  
22 ENCAPSULATION DEVICE IN PATIENTS IN ORDER TO  
23 OPTIMIZE FOR ITS USE AS PART OF THE COMBINATION  
24 PRODUCT.

25 THE PROPOSED ACTIVITIES ARE TO MANUFACTURE

BARRISTERS' REPORTING SERVICE

1 THE DIFFERENT CONFIGURATIONS OF THE DEVICE AND SOME  
2 QUALITY CONTROL, TO ENROLL SUBJECTS INTO THIS  
3 CLINICAL TRIAL, AND ANALYZE THE OUTCOMES OF THE  
4 DATA.

5 THE FUNDS REQUESTED IS 2.6 MILLION, AND  
6 THE APPLICANTS ARE PROVIDING 1.2 MILLION IN  
7 CO-FUNDING, WHICH IS ABOUT 30 PERCENT.

8 THEN IN MY LAST SLIDE IS AN OVERVIEW OF  
9 THE REVIEW ITSELF. AS YOU KNOW, WE CONDUCT AN  
10 INTERNAL BUDGET REVIEW TO ENSURE THAT COSTS CLAIMED  
11 IN THE BUDGET ARE ALL REASONABLE. SO THE  
12 APPLICATION PASSED THE BUDGET REVIEW.

13 THEN AT THE GRANTS WORKING GROUP REVIEW,  
14 THE APPLICATION RECEIVED A SCORE OF 1. THIS CAME  
15 ABOUT BECAUSE THERE WERE FIVE SCIENTIFIC MEMBERS WHO  
16 GAVE IT A SCORE OF 1, FIVE OTHER MEMBERS GAVE IT A  
17 SCORE OF 2, AND ONE GAVE IT A SCORE OF 3.

18 SO AS INDICATED BEFORE HERE, WE HAVE A  
19 SITUATION WHERE THERE WAS NO PLURALITY OR A MAJORITY  
20 ACHIEVED. THEREFORE, A VOTE BY ALL GRANTS WORKING  
21 GROUP MEMBERS WAS SOUGHT. A MOTION TO ASSIGN A  
22 SCORE OF 1 WAS MADE, AND THAT VOTE PASSED WITH NINE  
23 YES VOTES, EIGHT NO VOTES, AND ONE ABSTENTION.

24 CIRM'S RECOMMENDATION IS BASICALLY  
25 RECOMMENDING A 2, WHICH IS TO NOT FUND BUT ALL

BARRISTERS' REPORTING SERVICE

1 REVISION AND IMMEDIATE RESUBMISSION FOR THE GRANTS  
2 WORKING GROUP EVALUATION. AND THIS IS BASED ON THE  
3 SCORING SYSTEM WHERE WE FEEL THAT THE OUTCOME OF THE  
4 SCORE IS NOT AN ACCURATE REPRESENTATION OF THE SENSE  
5 OF THE WORKING GROUP. SO THIS IS REALLY A FLAW, WE  
6 FEEL, IN THE SCORING SYSTEM THAT WE HOPE TO CORRECT  
7 GOING FORWARD. BUT BY ASSIGNING A SCORE OF 2, THIS  
8 GIVES THE APPLICANT AN OPPORTUNITY TO ADDRESS THE  
9 CONCERNS THAT WERE BROUGHT UP BY THE GRANTS WORKING  
10 GROUP AND THEN ALLOW THE GRANTS WORKING GROUP TO  
11 PROVIDE A MORE ROBUST RECOMMENDATION WITH THOSE  
12 CONCERNS ADDRESSED.

13 SO THAT --

14 MR. SHEEHY: SO I THINK THE NEXT STEP  
15 WOULD BE TO GO INTO CLOSED SESSION SO THAT WE CAN  
16 TALK ABOUT PROPRIETARY OR CONFIDENTIAL INFORMATION  
17 CONTAINED IN THE GRANT. AND ONE OF THE REASONS  
18 WE'RE DOING THAT IS THE CLOSE VOTE. AND ALSO THIS  
19 IS AN APPLICANT THAT WE'VE BEEN WORKING WITH FOR A  
20 NUMBER OF YEARS, AND WE DO NEED TO DISCUSS WHAT'S  
21 BEEN HAPPENING WITH THIS GRANT UP TO THIS POINT.

22 BUT I HAD ONE QUICK -- IF EVERYBODY IS  
23 OKAY WITH THAT, THEN WE CAN REALLY TALK ABOUT THE  
24 GRANT AFTERWARDS, BUT I THINK IT WOULD BE HELPFUL  
25 FOR PEOPLE TO BE ABLE TO -- WE HAVEN'T DONE THIS FOR



BARRISTERS' REPORTING SERVICE

1 A LONG TIME. WE USED TO DO IT ALL THE TIME, BUT I  
2 THINK IN THIS PARTICULAR INSTANCE, GOING INTO CLOSED  
3 SESSION WILL ALLOW PEOPLE TO REALLY ASK THE TYPES OF  
4 QUESTIONS AND GET THE ANSWERS THEY NEED TO REALLY  
5 UNDERSTAND WHAT'S GOING ON HERE.

6 BEFORE WE DO THAT, ONE POINT OF  
7 CLARIFICATION ON THE CIRM TEAM RECOMMENDATION. THIS  
8 REALLY RELATES TO THE SCORING ALONE, RIGHT?

9 DR. SAMBRANO: RIGHT.

10 MR. SHEEHY: OKAY. SO YOU'RE NOT MAKING A  
11 DECISION ABOUT THE MERIT OF THE APPLICATION, BUT  
12 REALLY THE FLAW IN THE SCORING SYSTEM WHERE WE HAVE  
13 A GRANT RECOMMENDED FOR FUNDING BUT DID NOT GET THE  
14 MAJORITY OF THE WORKING GROUP TO SUPPORT IT. SO  
15 WITH THAT, CLOSED SESSION PLEASE.

16 MS. BONNEVILLE: BOARD MEMBERS, WE SENT  
17 YOU THE CLOSED SESSION NUMBER. YOU WILL HAVE TO  
18 OBVIOUSLY HANG UP ON THIS LINE, CALL BACK INTO THAT  
19 LINE, AND THEN DO THE SAME WHEN WE'RE BACK. IF YOU  
20 NEED THE NUMBER, LET ME KNOW AND I WILL E-MAIL IT TO  
21 YOU.

22 MR. TOCHER: AND WE WILL BE ADJOURNING TO  
23 CLOSED SESSION PURSUANT TO HEALTH AND SAFETY CODE  
24 SECTION 125290.30(F)(3)(B AND C) TO DISCUSS THE  
25 CONFIDENTIAL AND INTELLECTUAL PROPERTY OR WORK

BARRISTERS' REPORTING SERVICE

1 PRODUCT, PUBLICATION DATA, FINANCIAL INFORMATION,  
2 CONFIDENTIAL SCIENTIFIC RESEARCH OR DATA REGARDING  
3 THE GRANT AT ISSUE.

4 MR. SHEEHY: THANKS.

5 (THE APPLICATION REVIEW SUBCOMMITTEE  
6 THEN WENT INTO CLOSED SESSION, NOT REPORTED NOR  
7 HEREIN TRANSCRIBED. THE MEETING WAS THEN RECONVENED  
8 IN OPEN SESSION AND WAS HEARD AS FOLLOWS:)

9 MR. SHEEHY: ARE WE BACK? SO NEXT STEP  
10 WOULD BE A MOTION TO EITHER FUND THIS OR NOT FUND  
11 THIS. I'LL TAKE A MOTION EITHER DIRECTION. DO I  
12 HAVE A MOTION?

13 DR. HIGGINS: JEFF, I HAVE A QUESTION  
14 BEFORE YOU DO THAT. THIS IS DAVID.

15 MR. SHEEHY: PLEASE.

16 DR. HIGGINS: IF YOU VOTE NOT TO FUND IT,  
17 ARE WE GIVING IT A 2? ARE WE ASSIGNING IT AS A 2?

18 MR. SHEEHY: LET'S CLARIFY. YEAH. A  
19 MOTION TO EITHER MAKE IT A 2 OR TO FUND, WHY DON'T  
20 WE LOOK AT THOSE.

21 DR. HIGGINS: GREAT. THANK YOU.

22 MR. SHEEHY: THAT'S A GREAT CLARIFICATION.  
23 THANKS, DAVID.

24 DR. JUELGAARD: I MOVE THAT WE MOVE THIS  
25 TO TIER II, PLEASE.

BARRISTERS' REPORTING SERVICE

1 UNIDENTIFIED SPEAKER: SECOND.

2 MR. SHEEHY: OKAY. SO WE HAVE THE MOTION.  
3 DO I HAVE DISCUSSION?

4 DR. PRIETO: JEFF?

5 MR. SHEEHY: YES.

6 DR. PRIETO: THIS IS FRANCISCO. SO THE  
7 RECOMMENDATION OF THE CIRM TEAM TO MAKE THIS A 2 IS  
8 BASED SPECIFICALLY ON THE PROCESS ISSUES, THE  
9 CONFUSION ENGENDERED BY OUR SCORING SYSTEM AND HOW  
10 THIS ONE HAPPENED TO BREAK DOWN BECAUSE THERE WAS A  
11 TIE BETWEEN TIER I, TIER II, WITH ONE OUTLIER IN  
12 TIER III. THE GWG BROKE THAT TIE BY MOVING IT INTO  
13 TIER I. I THINK IF WE'RE GOING TO MOVE IT INTO TIER  
14 II, WE'RE SAYING THIS PROCESS IS REALLY FLAWED AND  
15 WE NEED TO REJIGGER IT, BUT WE ARE CHANGING THE  
16 RULES AFTER THE GAME STARTS. I THINK THAT MAY BE  
17 OKAY.

18 IF THAT HAPPENS, THEN WHAT GOES BACK TO  
19 THE COMPANY IS A REVISION DOCUMENT FROM CIRM  
20 REFLECTING THE RECOMMENDATIONS FROM THE GWG  
21 REVIEWERS. AND THERE ARE BASICALLY THREE ISSUES  
22 THAT WOULD GO BACK TO VIACYTE.

23 ONE IS THAT SOME OF THE REVIEWERS THOUGHT  
24 THAT MORE PRELIMINARY ANIMAL DATA WAS NEEDED FOR THE  
25 DIFFERENT CONFIGURATIONS OF THEIR DEVICE THAT

BARRISTERS' REPORTING SERVICE

1 THEY'RE LOOKING AT, TO LOOK AT THE ANIMAL FOREIGN  
2 BODY RESPONSE. AS I SAID IN CLOSED SESSION, I THINK  
3 WE'RE PAST THAT POINT BECAUSE I THINK THE ISSUES NOW  
4 ARE THE HUMAN FOREIGN BODY RESPONSE. THE OTHERS ARE  
5 TRIAL DESIGN. PEOPLE WANTED MORE COMPARATORS OF  
6 BASICALLY THE EMPTY VERSUS THE FULL DEVICE, EMPTY  
7 VERSUS FULL VERSIONS OF THE DIFFERENT VERSIONS OF  
8 THE CURRENT DEVICE, AND THEN PERHAPS RELATED TO THAT  
9 WHETHER THE STUDY HAS SUFFICIENT POWER, THE NUMBER  
10 OF SUBJECTS AND THE NUMBER OF VARIABLES THAT THEY'RE  
11 LOOKING AT. THE NUMBER OF SUBJECTS IS RELATIVELY  
12 SMALL AND THE NUMBER OF VARIABLES IS LARGE. SO IF  
13 WE WANT THIS TO HAVE MORE STATISTICAL POWER AND MORE  
14 MEANINGFUL RESULTS, THEN WE'RE LOOKING AT THE  
15 COMPANY COMING BACK WITH A STUDY PROPOSAL THAT WOULD  
16 MEAN MORE SUBJECTS AND MORE FUNDING.

17 I'M OKAY WITH THAT, BUT I JUST WANT TO BE  
18 CLEAR THAT IN MY MIND THAT'S WHAT WE'RE LOOKING AT  
19 IF WE'RE MOVING THIS INTO TIER II.

20 MR. SHEEHY: CHAIRMAN THOMAS.

21 CHAIRMAN THOMAS: JEFF, I WANT TO FOLLOW  
22 THAT, IF I MAY. WE HAVE THE GRANTS WORKING GROUP  
23 PUBLIC REVIEW SUMMARY THAT WAS DEVELOPED AND A  
24 RESPONSE TO THAT AND THEN BY THE COMPANY. MY  
25 QUESTION TO THE TEAM IS HOW DO YOU FEEL THE COMPANY

BARRISTERS' REPORTING SERVICE

1       ADDRESSED THE ISSUES RAISED IN THE PUBLIC REVIEW  
2       SUMMARY?

3                   DR. SAMBRANO:   SO THIS IS GIL.   WE REALLY  
4       RELY ON THE GRANTS WORKING GROUP TO GIVE US A  
5       SCIENTIFIC OPINION ON THE MERITS OF AN APPLICATION.  
6       SO THE APPLICANTS HAVE RESPONDED TO SOME OF THE  
7       SPECIFIC CONCERNS THAT WERE RAISED, AND THE ONLY  
8       THING THAT WE WOULD BE ABLE TO OFFER IS THAT THE GWG  
9       WOULD NEED TO LOOK AT THAT EXPLANATION AND THE DATA  
10      TO REALLY DETERMINE WHETHER IT MEETS AND ADDRESSES  
11      THE CONCERNS OR NOT.

12                   I THINK THE INFORMATION THAT CONTAINS  
13      CERTAINLY IS SOMETHING THAT COULD BE PROVIDED TO THE  
14      GRANTS WORKING GROUP.   I THINK THE GRANTS WORKING  
15      GROUP WOULD WELCOME IT AND WOULD BE HAPPY TO PROVIDE  
16      A RESPONSE AS TO WHETHER THIS DOES OR DOES NOT MEET  
17      THE CRITERIA THEY HAD IN MIND FOR THOSE THAT FELT IT  
18      WAS NOT ADEQUATE ENOUGH.   FOR THOSE THAT FELT THIS  
19      WAS FINE WHERE IT WAS REMAINS WHERE THEY ARE.   BUT  
20      IT REALLY IS UP TO THE GWG TO ULTIMATELY MAKE THAT  
21      ADJUSTMENT.

22                   DR. STEWARD:   COULD I MAKE A COMMENT?

23                   DR. DULIEGE:   I'D LIKE TO MAKE A COMMENT  
24      WHEN IT IS POSSIBLE.

25                   MR. SHEEHY:   PLEASE, ANNE-MARIE.   AND WHO

BARRISTERS' REPORTING SERVICE

1 ELSE WANTS TO MAKE A COMMENT?

2 MR. PANETTA: THIS IS JOE PANETTA, JEFF,  
3 IF YOU CAN PLACE ME IN LINE.

4 MS. LAPORTE: THIS IS KATHY. I WAS JUST  
5 GOING TO ASK A TIMING QUESTION ON HOW LONG IT WOULD  
6 TAKE TO CYCLE BACK TO THE GWG.

7 MR. SHEEHY: OKAY. AND WHO ELSE WANTS TO  
8 ASK A QUESTION OR COMMENT?

9 DR. JUELSGAARD: STEVE JUELSGAARD.

10 MR. SHEEHY: OKAY. STEVE. SO THE FIRST  
11 IS ANNE-MARIE.

12 DR. DULIEGE: VERY BRIEFLY. I THINK THIS  
13 IS REALLY A PROCESS ISSUE IN KNOWING WHEN THERE'S  
14 ADDITIONAL INFORMATION COMMENT, IT GOES BACK TO THE  
15 GWG AND COMES BACK TO US. IN THE PAST WE HAVE SHOWN  
16 FLEXIBILITY BOTH IN THE ICOC LEVEL AND AT THE CIRM  
17 LEVEL WHEN THERE WAS AN ACTUAL OR PERCEIVED URGENCY  
18 TO HAVE A RESPONSE BACK.

19 SO MY QUESTION IS BACK TO WHAT KATHY  
20 MENTIONED, WHICH IS HOW LONG IT WILL TAKE FOR THE  
21 GWG TO LOOK AT THE QUESTION AND GET BACK TO THE  
22 ICOC.

23 IF I MAY ASK A SECOND QUESTION, I WAS A  
24 LITTLE CONFUSED BY THE LAST SLIDE. IT SAYS THAT  
25 THERE WAS A VOTE FOR A SCORE 1 OF FIVE PEOPLE. AND

BARRISTERS' REPORTING SERVICE

1 THEN THERE'S A FOOTNOTE SAYS VOTE BY THE GWG TO  
2 ASSIGN A SCORE OF 1, NINE YES, EIGHT NO, ONE  
3 ABSTENTION. I'M GETTING A LITTLE CONFUSED BETWEEN  
4 THIS. IF SOMEONE CAN CLARIFY. THANK YOU.

5 DR. SAMBRANO: SURE. TO ADDRESS THE FIRST  
6 QUESTION IN TERMS OF TIMING, THAT CAN HAPPEN VERY  
7 QUICKLY, AND OFTEN IT HAPPENS WITHIN A MONTH. SO IN  
8 THIS PARTICULAR CASE, DEPENDING ON HOW QUICKLY THE  
9 APPLICANT PROVIDES A RESPONSE TO THE COMMENTS, IT IS  
10 LIKELY THAT WE CAN TAKE IT TO THE SEPTEMBER GWG  
11 REVIEW. SO IT WOULD BE ABOUT A MONTH AND THEN WOULD  
12 COME BACK TO THE ICOC IN OCTOBER.

13 NOW, REGARDING YOUR QUESTION ABOUT THE  
14 SCORE, SO THE VOTE'S SHOWN AS FIVE, FIVE, AND ONE  
15 REPRESENTS THE SCORES BY THE SCIENTIFIC MEMBERS.  
16 AND SO WHEN WE TALLIED THOSE VOTES, IF THERE IS A  
17 PLURALITY OR A MAJORITY, THAT'S WHAT DETERMINES THE  
18 OUTCOME. IN THIS CASE, BECAUSE THE FIVE, FIVE, ONE  
19 HAS NO PLURALITY AND NO MAJORITY, WHAT HAPPENS THEN  
20 IS WE TAKE A MOTION FROM ANY MEMBER OF THE GRANTS  
21 WORKING GROUP, THAT IS, THE SCIENTIFIC MEMBERS PLUS  
22 THE PATIENT ADVOCATE MEMBERS, AND THAT'S WHY THE  
23 TOTAL NUMBER IS DIFFERENT, AND THE MOTION IN THIS  
24 CASE WAS TO ASSIGN IT A SCORE OF 1. THAT MOTION WAS  
25 SECONDED, AND THEN WE TOOK A ROLL CALL VOTE ON THAT

BARRISTERS' REPORTING SERVICE

1 MOTION TO ASSIGN THE SCORE OF 1. AND THAT'S NINE,  
2 EIGHT, AND ONE.

3 MR. SHEEHY: SO BEFORE I RECOGNIZE JOE, I  
4 JUST WANT TO MAKE A QUICK COMMENT. SO FOR THOSE WHO  
5 HAVE TO LEAVE AT NOON, THERE IS A PROVISION IN THE  
6 ICOC BYLAWS THAT CAN ALLOW YOU TO REGISTER A VOTE.  
7 SO IF YOU HAVE A HARD STOP AND YOU'RE ABOUT TO SIGN  
8 OFF, AND I HOPE WE'LL ALL BE KIND TO EACH OTHER,  
9 MAYBE YOU COULD JUST KIND OF POLITELY INTERRUPT AND  
10 SAY I HAVE TO GO AND I WOULD LIKE TO RECORD A VOTE  
11 OF YES OR NO ON THIS MOTION. AND THIS MOTION IS TO  
12 PUT THE APPLICATION IN TIER II.

13 BUT, JOE, I THINK YOU'RE NEXT UP.

14 DR. DULIEGE: THANKS FOR THE RESPONSE.  
15 IT'S HELPFUL. SECOND. I WILL HAVE TO LEAVE IN FOUR  
16 MINUTES. I WOULD LIKE TO REGISTER MY VOTE OF BEING  
17 IN FAVOR OF THE MOTION TO SEND THIS BACK TO THE GWG  
18 VIA A SCORE OF 2.

19 MR. SHEEHY: THANKS, ANNE-MARIE.

20 MR. TOCHER: IF I CAN JUST INTERRUPT, THIS  
21 IS SCOTT TOCHER. THE BYLAWS PROVIDE, HOWEVER, THAT  
22 THERE IS A LIMIT. THERE ARE SOME LIMITATIONS ON  
23 THIS, AND THE NUMBER IS FIVE. SO WE CAN ONLY GO SO  
24 FAR. BUT THANKS, ANNE-MARIE.

25 MR. SHEEHY: OKAY. JOE.



BARRISTERS' REPORTING SERVICE

1 MR. PANETTA: THANKS, JEFF. I GUESS IT'S  
2 MORE OF A PROCEDURAL COMMENT THAN ANYTHING THAT I  
3 HAVE IN THAT I THINK IT'S A LITTLE CONFUSING TO THE  
4 COMMITTEE TO BE PRESENTED WITH THIS LETTER THAT  
5 VIACYTE SENT IN -- THAT THE APPLICANT SENT IN ON  
6 AUGUST 21ST WITHOUT REALLY AT THIS POINT BEING ABLE  
7 TO, IT SOUNDS, WITHOUT BEING ABLE TO REALLY ASSESS  
8 IT IN ANY WAY. SO I'M NOT REALLY SURE WHAT THE  
9 PURPOSE OF US BEING PRESENTED WITH THIS LETTER  
10 BECAUSE IT SOUNDS AS IF, AND I WOULD AGREE, THAT A  
11 MORE IN-DEPTH ANALYSIS NEEDS TO BE DONE AND  
12 PRESENTED TO THE APPLICATION REVIEW SUBCOMMITTEE  
13 BEFORE WE CAN CONSIDER THE RESPONSE THAT THE  
14 APPLICANT MADE. SO I GUESS I'M SAYING BASICALLY I'M  
15 NOT SURE WHY WE'RE SEEING THIS LETTER.

16 DR. MILLS: THAT LETTER AND OTHERS ARE  
17 PART OF THE PROCESS WHERE THE PUBLIC IS ALLOWED TO  
18 COMMENT. AND SO THE APPLICANT, ALSO BEING PART OF  
19 THE PUBLIC, IS ALLOWED TO MAKE PUBLIC COMMENT. SO  
20 THAT'S WHY THAT LETTER IS THERE.

21 MR. PANETTA: SO WHAT WE'RE REALLY HEARING  
22 FROM THE STAFF IS THIS IS REALLY NOT FOR YOU TO BE  
23 ABLE TO TAKE A LOOK AT AND DECIDE WHETHER WE SHOULD  
24 GO FORWARD WITH THE APPLICATION BASED ON THIS  
25 INFORMATION?

BARRISTERS' REPORTING SERVICE

1 DR. MILLS: IT'S JUST A PUBLIC COMMENT.  
2 IT'S NOT BEING ADJUDICATED BY CIRM.

3 MR. PANETTA: THANK YOU.

4 MR. SHEEHY: KATHY, DID YOU STILL HAVE A  
5 QUESTION OR DID YOURS GET ANSWERED?

6 MS. LAPORTE: MINE GOT ANSWERED. THANKS,  
7 JEFF.

8 MR. SHEEHY: OS, I HAVE YOU NEXT.

9 DR. STEWARD: JUST A QUICK COMMENT. IN  
10 PRINCIPLE I THINK THAT IT IS IMPOSSIBLE FOR THE ICOC  
11 TO MAKE ANY JUDGMENTS ON CLAIMS RELATED TO DATA OR  
12 FINDINGS MADE AS PART OF A SUBMISSION LETTER. SO I  
13 THINK ANYTHING LIKE THAT HAS TO GO BACK TO THE  
14 EXPERTS OF THE GRANTS WORKING GROUP; AND, THEREFORE,  
15 I SUPPORT THE MOTION.

16 MR. SHEEHY: STEVE.

17 DR. JUELSGAARD: TWO POINTS. THE FIRST  
18 IS, AND BACK TO WHAT FRANCISCO TALKED ABOUT IN TERMS  
19 OF PROCESS, SO I ACTUALLY DON'T SEE THIS AS GOING  
20 AGAINST THE PROCESS. THIS COMMITTEE NEEDS TO EITHER  
21 ACCEPT THE RECOMMENDATIONS OF THE GWG OR NOT. AND  
22 IT'S ALWAYS FREE TO MOVE SOMETHING FROM TIER I TO  
23 TIER II IF IT BELIEVES THAT, THIS COMMITTEE  
24 BELIEVES, THAT THAT'S THE BEST RESULT. SO EVEN  
25 THOUGH LARGER GROUP BELIEVE IT SHOULD BE IN TIER I

BARRISTERS' REPORTING SERVICE

1 DOESN'T BIND THE APPLICATION SUBCOMMITTEE FROM  
2 DECIDING THAT IT SHOULD BE IN TIER II. SO I JUST  
3 WANT TO RECOGNIZE THAT WE SEPARATELY MAKE OUR OWN  
4 DECISIONS AS THIS COMMITTEE.

5 THE SECOND THING, AND THIS REALLY HASN'T  
6 BEEN ADDRESSED YET, BUT FOR ME ONE OF THE MOST  
7 TELLING THINGS ABOUT WHY I THINK THIS NEEDS FURTHER  
8 GWG REVIEW AND WAS NOT AMONGST THOSE THINGS THAT  
9 FRANCISCO POINTED OUT, AND IT COMES IN THE VERY  
10 FIRST RESPONSE OF THE GWG THAT'S ON THE THIRD SLIDE  
11 OF THE PUBLIC REVIEW SUMMARY. AND I'LL JUST READ IT  
12 VERBATIM BECAUSE THIS REALLY CAPTURES IT FOR ME.

13 "OVERCOMING THE FOREIGN BODY RESPONSE IS A  
14 DAUNTING TASK ATTEMPTED BY MANY IN THE ENCAPSULATION  
15 FIELD. THE APPLICATION DID NOT INCLUDE SUFFICIENT  
16 INFORMATION REGARDING HOW AND WHY MATERIALS FOR THE  
17 DEVICES WERE SELECTED, NOR DID IT PROVIDE EVIDENCE  
18 THAT THE PROPOSED DEVICE DESIGN WOULD DECREASE  
19 FOREIGN BODY RESPONSES. THERE IS NOT SUFFICIENT  
20 DATA IN THE APPLICATION FOR REVIEWERS TO THINK IT IS  
21 LIKELY THAT ANY OF THE PROPOSED CONFIGURATIONS OR  
22 DIFFERENT INSERTION SITES WILL BE SUCCESSFUL IN  
23 IMPROVING VASCULARIZATION OR DECREASING THE FOREIGN  
24 BODY RESPONSE TO ULTIMATELY IMPROVE ENGRAFTMENT OF  
25 THE COMBINATION PRODUCT."

BARRISTERS' REPORTING SERVICE

1 AND IT SEEMS TO ME THAT THAT'S A PREDICATE  
2 TO GOING FORWARD WITH THIS. WHAT'S THE SCIENTIFIC  
3 LITERATURE? WHAT'S THE SCIENTIFIC UNDERPINNINGS  
4 THAT SUGGEST THAT THESE DIFFERENT TECHNIQUES THAT  
5 THEY -- THAT VIACYTE SUGGESTS PROCEEDING WITH,  
6 WHAT'S THE UNDERLYING SCIENTIFIC RATIONALE WHERE IT  
7 SUGGESTS ANY ONE OF THEM MIGHT OVERCOME THE PROBLEMS  
8 THAT THEY'RE SEEING? AND AS I UNDERSTAND IT FROM  
9 THIS COMMENT, NOTHING LIKE THAT WAS PRESENTED. AND  
10 I WOULD BE HOPEFUL THAT IN THE NEXT GWG REVIEW,  
11 SHOULD THAT TAKE PLACE, SHOULD WE VOTE TO MOVE THIS  
12 TWO TIER, THAT THAT BE ADDRESSED. THAT'S IT.

13 MR. SHEEHY: OKAY. DO WE HAVE OTHER  
14 COMMENTS, QUESTIONS?

15 DR. MELMED: I'M SORRY. I HAVE TO STEP  
16 OUT. I'M SORRY. I HAVE TO END THE CALL.

17 MR. SHEEHY: THANK YOU, DR. MELMED.

18 MS. BONNEVILLE: THANK YOU.

19 MR. SHEEHY: I DID ACTUALLY HAVE A COMMENT  
20 MYSELF, AND THEN I'M GOING TO OPEN UP TO PUBLIC  
21 COMMENT BECAUSE WE HAVE PEOPLE FROM VIACYTE HERE.

22 I ACTUALLY AM IN SUPPORT OF THIS. AND I  
23 KNOW THAT WE'RE KIND OF CAUGHT UP ON THE NEW  
24 INFORMATION THAT'S COME IN, BUT I WAS ONE OF THE  
25 ONES WHO VOTED TO KEEP THIS IN TIER I. AND THE

BARRISTERS' REPORTING SERVICE

1 REASON WHY, AND EVEN AS MUCH AS I APPRECIATE WHAT  
2 STEVE HAD SAID ABOUT ADDITIONAL DATA IN THE  
3 MATERIALS, BUT A BIG ISSUE IN THIS WAS A LOT OF  
4 FOLKS THOUGHT THEY SHOULD GO BACK AND LOOK AT ANIMAL  
5 MODELS AND DO WORK IN ANIMALS. AND I THINK I WAS  
6 PERSUADED BY THE ARGUMENT THAT WAS MADE AT THE TIME,  
7 THAT ANIMAL MODELS ARE NOT GOING TO GIVE YOU  
8 SUFFICIENT INFORMATION, THAT THE ONLY WAY YOU'RE  
9 REALLY GOING TO FIGURE OUT WHAT'S HAPPENING AND HOW  
10 THEY ADDRESS THIS ROADBLOCK IS BY GOING INTO HUMANS.  
11 AND I FOUND THAT TO BE COMPELLING.

12 IN GOING BACK AND FORTH ON THIS, I THINK  
13 THIS MAY BE ONE OF THE ISSUES I THINK IS  
14 IRRESOLVABLE, WHETHER TO DO THIS PRECLINICAL WORK OR  
15 NOT. PEOPLE SAY YOU HAVE TO DO IT, BUT THERE WILL  
16 BE OTHER PEOPLE WHO WILL SAY THAT IT WON'T GIVE YOU  
17 THE INFORMATION THAT YOU NEED.

18 I FALL DOWN ON THE SECOND. SO I ACTUALLY  
19 WILL BE VOTING AGAINST THIS MOTION.

20 SO IF THERE ARE NO MORE COMMENTS OR  
21 QUESTIONS FROM MEMBERS OF THE BOARD --

22 DR. PADILLA: THIS IS ADRIANA. I HAD A  
23 QUESTION. WHAT'S THE TURNAROUND TIME FRAME FOR THE  
24 RE-REVIEW IF THE MOTION PASSES?

25 MR. SHEEHY: IT COULD BE 30 DAYS. A LOT

BARRISTERS' REPORTING SERVICE

1 DEPENDS ON THE APPLICANT OBVIOUSLY SUBMITTING  
2 RESPONSES TO THE QUESTIONS THAT WERE RAISED BY THE  
3 WORKING GROUP. BUT I SUSPECT THAT THIS LETTER  
4 CONTAINS A LOT OF THAT INFORMATION.

5 DR. PADILLA: OKAY. THANK YOU.

6 MR. SHEEHY: YOU'RE WELCOME.

7 MR. ROWLETT: JEFF, THIS IS AL ROWLETT. I  
8 DO HAVE A HARD STOP. AND I WILL VOTE YES IN FAVOR  
9 OF THE MOTION.

10 MR. SHEEHY: GREAT. THANKS, AL.

11 SO COMMENTS, QUESTIONS?

12 DR. STEWARD: THIS IS OS.

13 MS. LAPORTE: I APOLOGIZE. I HAVE A HARD  
14 STOP TOO. I WILL VOTE NO OR AGAINST THE MOTION FOR  
15 BASICALLY THE SAME REASONS YOU JUST ELABORATED.

16 MR. SHEEHY: THANK YOU, KATHY. OS.

17 DR. STEWARD: JUST TO SAY, BEFORE WE  
18 ACTUALLY CALL FOR PUBLIC COMMENT, I WOULD ASK ANY  
19 WHO ARE GOING TO SPEAK TO PLEASE RESPECT THE  
20 THREE-MINUTE LIMIT. THERE ARE MANY PEOPLE WHO DO  
21 HAVE HARD STOPS HERE; AND IF WE'RE GOING TO HAVE A  
22 VOTE TODAY, THEN WE'RE GOING TO NEED TO GET TO THAT  
23 VOTE.

24 MR. SHEEHY: GREAT. THANK YOU, DR.

25 STEWARD.

BARRISTERS' REPORTING SERVICE

1 SO THERE'S SOMEONE AT JOE PANETTA'S  
2 OFFICE, BUT I THINK WE'LL START HERE IN SAN  
3 FRANCISCO WITH PUBLIC COMMENT. IS THERE ANYBODY WHO  
4 WANTS TO ADDRESS? OKAY. IT WOULD BE HELPFUL IF YOU  
5 COME TO THE TABLE SO THAT EVERYBODY CAN HEAR YOU ON  
6 THE PHONE.

7 MS. COLES: HI. MY NAME IS EMILY COLES  
8 (PHONETIC). I'M NOT AFFILIATED WITH VIACYTE. I'M A  
9 PATIENT ADVOCATE. I'M JUST A PERSON WHO HAS TYPE 1  
10 DIABETES. AND MAINLY WHY I CAME AND WHAT I WANTED  
11 TO REPRESENT TODAY WAS A TINY LITTLE PIECE OF THE  
12 EXPERIENCE OF HAVING DIABETES AND WHY I FEEL A SENSE  
13 OF URGENCY FOR THIS TO MOVE FORWARD. AND FIRST I  
14 WANT TO THANK CIRM FOR THE SUPPORT IT HAS ALREADY  
15 GIVEN TO VIACYTE.

16 I WANT TO DEMONSTRATE MY POINT ABOUT THE  
17 URGENCY WITH A STORY. AND THE STORY IS THAT A FEW  
18 MONTHS AGO I WAS ASLEEP ON MY SOFA WITH MY PARTNER.  
19 I WAS WATCHING A MOVIE, AND I HAD DOZED OFF. AND I  
20 WOKE UP UNABLE TO SPEAK AND UNABLE TO MOVE, ABLE TO  
21 OPEN MY EYES, AND WITH THE REALIZATION THAT I WAS  
22 HAVING AN INSULIN REACTION. THE BLOOD SUGAR WAS LOW  
23 AND I WAS UNABLE TO FUNCTION. SO I COULDN'T CONVEY  
24 IT TO MY PARTNER WHAT WAS GOING ON. SHE DIDN'T KNOW  
25 WHAT WAS HAPPENING.

BARRISTERS' REPORTING SERVICE

1 AND SO WE SPENT A MOMENT STARING AT EACH  
2 OTHER, AND IN MY BRAIN I WAS SORT OF SCREAMING I  
3 NEED YOUR HELP AND SHE'S TRYING TO FIGURE OUT WHAT'S  
4 HAPPENING. THIS IS NOT RARE. THIS ISN'T WEIRD.  
5 THIS HAPPENS TO PEOPLE WITH DIABETES ALL THE TIME.  
6 WE HAVE AN EMERGENCY THAT COMES AT US OUT OF THE  
7 BLUE WHICH WE NEED SOMEBODY ELSE'S HELP TO SAVE.

8 I ACTUALLY HAD AN INCREDIBLY LOW BLOOD  
9 SUGAR ON THE WAY HERE THIS MORNING DRIVING MY CAR  
10 ACROSS THE BRIDGE. I SAVE MY OWN LIFE EVERY SINGLE  
11 DAY. I DON'T MAKE IT THROUGH A 24-HOUR PERIOD  
12 WITHOUT AN EMERGENCY THAT REQUIRES MY IMMEDIATE  
13 INTERVENTION. AND SO THAT'S WHY I FEEL SUCH A SENSE  
14 OF URGENCY AROUND THE WORK THAT VIACYTE IS DOING  
15 BECAUSE THEY ARE MY -- CURRENTLY MY ABSOLUTE BEST  
16 HOPE TO BE RELIEVED FROM THIS SITUATION.

17 I'VE HAD DIABETES FOR 38 YEARS. I HAVE  
18 THE BEST TECHNOLOGY THAT IS CURRENTLY AVAILABLE TO  
19 COPE WITH DIABETES. I HAVE A WORLD RENOWN  
20 ENDOCRINOLOGIST. I HAVE ALL THE INFORMATION A  
21 PERSON COULD POSSIBLY HAVE ABOUT MANAGING DIABETES  
22 AT MY FINGERTIPS. AND EVERY SINGLE DAY AND MOST  
23 NIGHTS I FACE AN IMMEDIATE EMERGENCY, AND I NEED TO  
24 COME TO MY OWN RESCUE OR FIND SOMEONE ELSE WHO CAN  
25 COME TO MY RESCUE.



BARRISTERS' REPORTING SERVICE

1           THIS ISN'T THE SAME WITH EVERYONE WHO HAS  
2           TYPE 1 DIABETES, BUT IT IS NOT RARE. IT IS A  
3           COMMON, COMMON STORY FOR FOLKS WITH DIABETES. SO I  
4           LOOK FORWARD TO IMPART THAT TO THIS GROUP HOW EVEN A  
5           SMALL DELAY MEANS THAT MANY MORE NIGHTS OF FALLING  
6           ASLEEP SCARED OF WHAT WILL HAPPEN AT NIGHT TO THOSE  
7           OF US WHO FACE THIS. THANKS VERY MUCH.

8           MR. SHEEHY: THANK YOU.

9           MR. COLES: THANK YOU. MY NAME IS STATON  
10          COLES. I'M EMILY'S FATHER. SHE'S MY PRIDE AND JOY.  
11          SHE CAN SPEAK WITHOUT NOTES. I HAD ACTUALLY A FAIR  
12          NUMBER OF POINTS I WANT TO MAKE THOUGH I'VE WRITTEN  
13          THIS DOWN. THE ONLY WAY I CAN GET THROUGH IT IS TO  
14          READ IT IF THAT'S ALL RIGHT. BUT THANK YOU FOR  
15          GIVING US THE OPPORTUNITY.

16          I WANTED TO URGE YOU TO APPROVE THE GRANT  
17          AND MOVE FORWARD WITH THIS CRITICAL, IMPORTANT  
18          CLINICAL TRIAL. I'M SPEAKING TO YOU TODAY BOTH AS A  
19          DAD AND AS A LAY VOLUNTEER AT JDRF.

20          SO YOU JUST HEARD SOME OF EMILY'S STORY.  
21          OUR FAMILY HAS BEEN DEALING WITH THIS TERRIBLE  
22          DISEASE FOR ALMOST 40 YEARS. MY WIFE AND I WORRY  
23          ABOUT THE DEVASTATING CHRONIC COMPLICATIONS THAT  
24          MIGHT AFFECT EMILY, BUT WE ALSO WORRY ABOUT HER  
25          ACUTE DEATH. THE RISK OF SUDDEN DEATH DUE TO LOW

BARRISTERS' REPORTING SERVICE

1 BLOOD SUGAR IS DISTRESSINGLY HIGH, AS YOU'VE JUST  
2 HEARD FROM EMILY.

3 I HAD A FRIEND WITH TYPE 1 DIABETES WHO  
4 WAS A PHYSICIAN WHO DIED IN HER SLEEP OF LOW BLOOD  
5 SUGAR. SO THIS CAN HAPPEN TO THE MOST INFORMED AND  
6 DILIGENT PATIENTS. SO YOU UNDERSTAND OUR DEEP  
7 CONCERN WHEN EMILY, USING THE BEST TECHNOLOGIES  
8 AVAILABLE TODAY, REPORTS TO US THE DANGEROUSLY LOW  
9 BLOOD SUGAR LEVEL SHE SOMETIMES EXPERIENCES. THE  
10 SUCCESSFUL DEVELOPMENT OF VIACYTE'S ENCAPTRA PRODUCT  
11 WOULD LITERALLY BE A LIFESAVER FOR HER.

12 AFTER EMILY WAS DIAGNOSED, I WANTED TO DO  
13 EVERYTHING I COULD TO HELP FIND A CURE. I GOT  
14 HEAVILY INVOLVED AS A VOLUNTEER WITH JDRF. I SERVED  
15 ON THE INTERNATIONAL BOARD OF JDRF AND AS CHAIR OF  
16 THEIR RESEARCH COMMITTEE. I FOLLOWED THE  
17 DEVELOPMENT OF VIACYTE FOR OVER TEN YEARS. VIACYTE  
18 IS TODAY THE WORLDWIDE LEADER IN THE FIELD OF ISLET  
19 CELL ENCAPSULATION. ITS PRODUCT, IF SUCCESSFULLY  
20 DEVELOPED, WOULD PROFOUNDLY TRANSFORM MY DAUGHTER'S  
21 LIFE AND POTENTIALLY THE LIVES OF MILLIONS OF OTHERS  
22 LIVING WITH TYPE 1 DIABETES AND EVEN TYPE 2 DIABETES  
23 BY LIFTING THE SUBSTANTIAL DAILY BURDENS OF THIS  
24 DISEASE AND KEEPING THEM SAFE AND HEALTHY. IT'S A  
25 FUNCTIONAL CURE FOR THE DISEASE THAT CAN'T BE

BARRISTERS' REPORTING SERVICE

1 DEVELOPED TOO SOON FOR US.

2 I WANT TO SAY A FEW WORDS ABOUT THIS  
3 SPECIFIC APPLICATION. THE CLINICAL TRIAL VIACYTE IS  
4 PROPOSING COULD SUBSTANTIALLY INCREASE THE CHANCES  
5 OF SUCCESSFUL AND RAPID DEVELOPMENT OF AN EFFECTIVE  
6 AND MARKETABLE CELL THERAPY PRODUCT. WE HAVE  
7 LEARNED IN DIABETES RESEARCH THAT OUR BEST ANIMAL  
8 MODELS HAVE SUBSTANTIAL LIMITATIONS. THERE'S  
9 ABSOLUTELY NO WAY TO DETERMINE HOW A POTENTIAL  
10 THERAPY WILL WORK IN HUMANS OTHER THAN TESTING IT IN  
11 HUMANS. EVERYONE SEEMS TO AGREE THAT THE TRIAL  
12 DESIGN HERE IS SAFE AND ETHICAL. IT MUST PROCEED AS  
13 QUICKLY AS POSSIBLE.

14 SO I WANT TO THANK CIRM FOR ITS STRONG  
15 SUPPORT OF VIACYTE THROUGH THE YEARS, AND I URGE YOU  
16 TO APPROVE THIS CLINICAL TRIAL AND LET IT GO FORWARD  
17 AS QUICKLY AS POSSIBLE. THANK YOU.

18 MR. SHEEHY: THANK YOU. ADDITIONAL PUBLIC  
19 COMMENT HERE IN SAN FRANCISCO?

20 DR. LAIKIND: SO I'M PRESIDENT -- I'M PAUL  
21 LAIKIND. I'M PRESIDENT AND CEO OF VIACYTE. SO I  
22 APPRECIATE THE OPPORTUNITY TO COME UP AND TALK TO  
23 YOU ABOUT THIS TRIAL AND ABOUT THIS APPLICATION.

24 FIRST, I DO WANT TO THANK THE COMMITTEE.  
25 I WANT TO THANK CIRM FOR ALL THE SUPPORT THAT WE'VE

BARRISTERS' REPORTING SERVICE

1 HAD FROM YOU OVER THE COURSE OF THE DEVELOPMENT OF  
2 THIS PROGRAM. WE ARE REALLY TRYING TO CHANGE THE  
3 WORLD HERE WITH THIS APPROACH, REALLY DEVELOPING  
4 WHAT AMOUNTS TO A FUNCTIONAL CURE FOR TYPE 1  
5 DIABETES AND ALSO A POTENTIAL TREATMENT FOR TYPE 2  
6 PATIENTS WHO USE INSULIN.

7 SO WE'RE VERY EXCITED ABOUT THAT. WE'VE  
8 WORKED CLOSELY WITH CIRM. WE'VE GONE THROUGH A LOT  
9 OF DISCOVERY, EXTENSIVE PRECLINICAL DEVELOPMENT, AND  
10 CLINICAL EVALUATION TO GET TO WHERE WE ARE TODAY.

11 ONE POINT I WANTED TO MAKE IS I THINK WE,  
12 AS THE CIRM STAFF AND THE GROUP THAT WE WORK WITH AT  
13 CIRM KNOWS, WE'VE RUN INTO MANY ROADBLOCKS IN THIS  
14 PROGRAM. WE'VE HAD PLENTY OF CHALLENGES AND SUCH.  
15 BUT I THINK ONE OF THE THINGS THAT WE'RE REALLY  
16 PROUD OF, AND I THINK CIRM WOULD AGREE, THE CIRM  
17 STAFF WOULD AGREE WITH US, IS WE'VE GOT THE RIGHT  
18 TEAM. WE ADDRESSED THOSE ROADBLOCKS. WE DO ROOT  
19 CAUSE ANALYSIS TO UNDERSTAND WHAT'S GOING ON, AND  
20 THEN WE MAKE THE APPROPRIATE MOVES TO GET AROUND  
21 THEM. AND SO FAR, KNOCK ON WOOD, WE'VE BEEN  
22 SUCCESSFUL AND KEEP PUSHING THIS PROJECT FORWARD.

23 IT'S BEEN SAID A COUPLE TIMES HERE ABOUT  
24 THE IMPORTANCE OF THE CLINICAL EVALUATION. IT WAS  
25 INTERESTING WHEN YOU READ THE LEAD-IN OR SOMEBODY

BARRISTERS' REPORTING SERVICE

1 READ THE LEAD-IN, IN THE GWG'S COMMENTS, OR I THINK  
2 IT WAS STAFF COMMENTS ABOUT THAT ENCAPSULATION OF  
3 FOREIGN BODY RESPONSE HAS BEEN WORKED ON FOR A LONG  
4 TIME. IT'S BEEN WORKED ON FOR 30 YEARS.

5 WHY IS IT TAKING THAT LONG? WHY HAS IT  
6 GONE SO LONG? IT'S BECAUSE -- PART OF IT IS BECAUSE  
7 THE ANIMAL MODELS ARE IMPERFECT, AND WE DO NOT GET  
8 WHAT WE NEED FROM THE ANIMAL MODELS. THE IMMUNE  
9 SYSTEMS ARE DIFFERENT, THE ANATOMY IS DIFFERENT,  
10 EVERYTHING IS DIFFERENT. AND SO WE'VE LEARNED MORE  
11 IN THE LAST COUPLE YEARS SINCE WE MOVED THIS PRODUCT  
12 TO THE CLINIC THAN WE HAVE IN DECADES. AND THAT  
13 CONTINUES. AND SO I THINK WE HAVE CONDUCTED  
14 EXTENSIVE ANIMAL TESTING, INCLUDING TESTING OF THE  
15 DEVICES THAT ARE PART OF THIS GRANT, AND WE'VE  
16 LEARNED A LOT FROM THOSE STUDIES; BUT THE  
17 DIFFERENCES IN ANATOMY, IMMUNE PARTS, AND OTHER  
18 FACTORS LIMITS THE USEFULNESS OF THOSE RESULTS.

19 SO THE CLINICAL STUDIES ARE REALLY  
20 ACCELERATING OUR LEARNING, AND IT'S REALLY APPROVING  
21 THE ONLY RELEVANT MODEL FOR UNDERSTANDING WHAT'S  
22 GOING ON WITH REGARDS TO THAT FOREIGN BODY RESPONSE.  
23 WE NOW IMPLANTED AND EXPLANTED OVER A HUNDRED UNITS.  
24 THESE ARE THE DEVICES CONTAINING THE CELL SENTINELS  
25 AS WELL AS THE DOSE-RANGING DEVICES, AND WE'VE

BARRISTERS' REPORTING SERVICE

1 LEARNED A LOT FROM THAT. WE'VE DEMONSTRATED THAT  
2 THE DEVICES ARE DOING WHAT THEY'RE DESIGNED TO DO TO  
3 PROTECT AGAINST THE ADAPTIVE ROUTING SYSTEM. IT'S  
4 BEEN SAFE AND WELL TOLERATED. WE'VE LEARNED A LOT  
5 ABOUT WHAT'S GOING ON WITH THE FOREIGN BODY  
6 RESPONSE. AND ONE OF THE THINGS WE LEARNED WAS IT  
7 APPEARS THAT SOME CHANGES IN THE DEVICE COULD BE  
8 HELPFUL.

9 SO I THINK A COUPLE THINGS IMPORTANT TO  
10 UNDERSTAND IN RESPONSE TO ONE OF THE OTHER THINGS I  
11 HEARD WAS THERE'S NOT ENOUGH POWER. WE'RE PUTTING  
12 TEN DEVICES IN EACH OF THESE PATIENTS IN THIS TRIAL.  
13 SO IT'S LIKE DOING TEN ANIMALS EACH TIME, IF YOU  
14 WILL, IN SOME RESPECTS. SO WE GET A LOT OF DATA OUT  
15 OF EACH PATIENT IN THE TRIAL. SO IT'S MULTIPLYING.

16 THE OTHER THING I'D LIKE TO POINT OUT IN  
17 TERMS OF TIMING, A COUPLE MONTHS' DELAY, WHAT DOES  
18 THAT MEAN? WE HAVE INSTITUTIONAL REVIEW BOARD  
19 APPROVAL FOR THIS TRIAL IN CANADA AND THE U.S. AS WE  
20 SIT HERE TODAY. SO I'M PROUD OF WHAT WE'VE  
21 ACCOMPLISHED WITH CIRM'S HELP. WE ARE DOING REALLY  
22 IMPORTANT WORK HERE, AND WE ASK THAT THE ICOC FOLLOW  
23 THE RECOMMENDATION OF THE GRANTS WORKING GROUP AND  
24 GIVE A ONE AND APPROVE IT.

25 MR. SHEEHY: THANK YOU. DO WE HAVE

BARRISTERS' REPORTING SERVICE

1 ADDITIONAL PUBLIC COMMENT AT ANY OF THE SITES?

2 MS. STEELE: YES. LORRAINE STEELE IN MR.  
3 PANETTA'S OFFICE IN SAN DIEGO.

4 MR. SHEEHY: PLEASE.

5 MS. STEELE: THANK YOU. I AM HONORED TO  
6 SPEAK WITH ALL OF YOU TODAY AND SO PROUD OF MY  
7 PREVIOUS ASSOCIATION WITH BOTH PROP 71 AS A PATIENT  
8 ADVOCATE IN THE STATE OF CALIFORNIA AND ALSO WITH  
9 CIRM. EVEN THEY I'M INVOLVED IN NUMEROUS DIABETES  
10 ORGANIZATIONS, I SPEAK FOR MYSELF TODAY AND  
11 THOUSANDS OF PATIENTS I'VE MET WHO ARE EXCITED ABOUT  
12 REGENERATIVE MEDICINE IN TYPE 1 DIABETES.

13 I HAVE BEEN MARRIED TO A MAN OVER 30 YEARS  
14 WHO BASICALLY HAS EXPERIENCED ALMOST EVERY  
15 COMPLICATION IN TYPE 1 DIABETES. HE HAS HAD  
16 AMPUTATIONS, HE HAD KIDNEY TRANSPLANTS, HE HAD  
17 CRANIOTOMIES, HE'S HAD BRAIN SURGERY, STROKES. YOU  
18 NAME IT, MY HUSBAND HAS EXPERIENCED THOSE  
19 COMPLICATIONS. CLEARLY THE STANDARDS OF CARE THAT  
20 EXIST IN TYPE 1 DIABETES ARE NOT WORKING. WE REALLY  
21 TREAT THIS DISEASE SO CRUELY. MY HUSBAND LOVES TO  
22 SAY IT'S LIKE KILLING AN ANT WITH A Mallet.

23 THIRTY YEARS AGO TOMORROW I WALKED INTO MY  
24 FIRST ADVOCACY OFFICE IN DIABETES. I SPEAK AROUND  
25 THE STATE ON TYPE 1 DIABETES RESEARCH, AND I TALK TO

BARRISTERS' REPORTING SERVICE

1 THE MOST PASSIONATE OF FAMILIES. BEYOND EVERYTHING  
2 ELSE GOING ON IN TYPE 1 DIABETES, THE WORK THAT CIRM  
3 HAS BEEN FUNDING IN VIACYTE HAS CAPTURED THE  
4 ENTHUSIASM AND THE PASSION OF EVERY FAMILY. THEY  
5 ARE SO CONVINCED THIS IS THE ANSWER BECAUSE IT IS  
6 THE ONLY SOLUTION THAT HANDLES THE TWO PROBLEMS IN  
7 TYPE 1 DIABETES, A SOURCE OF CELLS AND THE ABILITY  
8 TO PROTECT THESE IMPORTANT LIFESAVING CELLS FROM THE  
9 IMMUNE SYSTEM.

10 I OFTEN QUOTE TO THESE FAMILIES THAT  
11 VIACYTE'S WORK FUNDED BY CIRM IS TEA BAG. PEOPLE  
12 GET THIS TEA BAG UNDERSTANDING AN APPROACH. I  
13 APPLAUD CIRM FOR HELPING VIACYTE TO BUILD THE BEST  
14 TEA BAG. AND I AM VERY EXCITED ABOUT THIS NEW  
15 CLINICAL TRIAL THAT THEY ARE EMBARKING HERE AND IN  
16 CANADA. NO OTHER GROUP HAS DONE THIS BEFORE.  
17 VIACYTE, CIRM, AND JDRF IS MAKING IT HAPPEN.

18 CIRM, THANK YOU FOR BEING THE STRONGEST OF  
19 PARTNERS THROUGH THIS ENTIRE PROCESS. I KNOW PAUL  
20 SAID THAT THIS HAS BEEN GOING ON FOR A WHILE AND A  
21 LOT OF CHALLENGES ALONG THE WAY. PATIENTS FEEL THAT  
22 EVERY DAY, BUT WE ALSO HAVE SUCH GREAT CONFIDENCE  
23 THAT THINGS WILL BE DONE CORRECTLY AND WE WILL GET  
24 TO THAT END POINT. TIMING IS EVERYTHING FOR OUR  
25 COMMUNITY AS THE PREVIOUS SPEAKER SHARED SO



BARRISTERS' REPORTING SERVICE

1 ELOQUENTLY.

2 NOW, EVERYBODY ASKS ME HOW SOON WE WILL  
3 GET THE TEA BAG. I HOPE THAT CIRM CONTINUES TO FUND  
4 RAPIDLY. WE TRUST CIRM TO DO THE RIGHT THING IN  
5 MOVING FORWARD THIS IMPORTANT LIFESAVING RESEARCH.  
6 THANK YOU.

7 MR. SHEEHY: THANK YOU, LORRAINE.

8 SO THANKS, EVERYONE, FOR YOUR COMMENTS.  
9 IS THERE ANY MORE PUBLIC COMMENT? IS THERE ANY MORE  
10 BOARD COMMENT OR ANY QUESTIONS FROM ANY BOARD  
11 MEMBERS?

12 DR. STEWARD: THIS IS OS, IF I COULD.

13 MR. SHEEHY: SURE. PLEASE.

14 DR. STEWARD: I JUST WANT TO THANK ALL THE  
15 PEOPLE WHO HAVE SPOKEN SO FORCEFULLY ON THE  
16 IMPORTANCE OF MOVING FORWARD AND THE URGENCY HERE.  
17 AND I JUST WANT YOU TO KNOW THAT ALL OF US ON THE  
18 BOARD AND ESPECIALLY, OF COURSE, THE PATIENT  
19 ADVOCATES TAKE THESE COMMENTS VERY SERIOUSLY. IT IS  
20 ALL ABOUT THE PATIENTS, AND WE ALL FEEL THE SENSE OF  
21 URGENCY. HOWEVER, SOMETIMES YOU CAN ACTUALLY MOVE  
22 FASTER IF YOU GET THINGS RIGHT. AND I THINK THAT'S  
23 WHAT WE'RE LOOKING AT HERE.

24 WHAT I SEE IS AN APPLICATION THAT HAS  
25 MAJOR STRENGTHS, BUT THERE ARE SOME ISSUES THAT

BARRISTERS' REPORTING SERVICE

1 COULD MAKE IT STRONGER, AND THAT MAKING IT STRONGER  
2 WOULD THEN MAKE THE WORK GO FASTER. AND THAT'S THE  
3 REASON THAT I SUPPORT THE ORIGINAL MOTION TO PUT  
4 THIS IN TIER II, WHICH MEANS THEY CAN COME BACK AS  
5 SOON AS 30 DAYS FROM NOW, AND HAVE THE OPPORTUNITY  
6 FOR THE GRANTS WORKING GROUP TO REVIEW THE NEW  
7 INFORMATION THOROUGHLY. THANK YOU.

8 MR. SHEEHY: ANY ADDITIONAL BOARD COMMENT  
9 OR QUESTIONS? THEN I THINK WE'RE AT A POINT,  
10 MS. BONNEVILLE, TO CALL THE ROLL PLEASE.

11 MS. BONNEVILLE: DAVID HIGGINS.

12 DR. HIGGINS: I'M GOING TO VOTE YES IN THE  
13 CONTEXT OF A QUICK TURNAROUND.

14 MS. BONNEVILLE: STEVE JUELSGAARD.

15 DR. JUELSGAARD: YES.

16 MS. BONNEVILLE: LAUREN MILLER.

17 MS. MILLER: YES.

18 MS. BONNEVILLE: ADRIANA PADILLA.

19 DR. PADILLA: YES.

20 MS. BONNEVILLE: JOE PANETTA.

21 MR. PANETTA: NO.

22 MS. BONNEVILLE: FRANCISCO PRIETO.

23 DR. PRIETO: NO.

24 MS. BONNEVILLE: ROBERT QUINT.

25 DR. QUINT: YES.

BARRISTERS' REPORTING SERVICE

1 MS. BONNEVILLE: JEFF SHEEHY.

2 MR. SHEEHY: NO.

3 MS. BONNEVILLE: OS STEWARD.

4 DR. STEWARD: YES.

5 MS. BONNEVILLE: JONATHAN THOMAS.

6 CHAIRMAN THOMAS: NO.

7 MS. BONNEVILLE: ART TORRES.

8 MR. TORRES: AYE.

9 MR. TOCHER: THE MOTION CARRIES BY A VOTE  
10 OF EIGHT AYE VOTES AND SIX NO VOTES.

11 MR. SHEEHY: THANK YOU. THAT CONCLUDES  
12 THE BUSINESS OF OUR APPLICATION REVIEW SUBCOMMITTEE,  
13 I BELIEVE. THAT'S OUR AGENDA.

14 CHAIRMAN THOMAS: THANK YOU, MR. SHEEHY.  
15 IS THERE ANY PUBLIC COMMENT ON ANYTHING IN GENERAL  
16 NOT PERTINENT TO THE DISCUSSION WE JUST HAD?  
17 HEARING NONE, WE -- TURN IT OVER TO AMY.

18 MS. CHEUNG: OUR NEXT ICOC MEETING IS  
19 SEPTEMBER 21ST IN SAN DIEGO. I SENT AN E-MAIL TO  
20 YOU THIS WEEK TO SEE IF YOU COULD ATTEND. IF YOU  
21 CAN PLEASE RESPOND TO ME, IF YOU HAVEN'T ALREADY,  
22 THAT WOULD BE GREAT. THANK YOU.

23 CHAIRMAN THOMAS: THANK YOU, EVERYBODY,  
24 VERY MUCH IN ALL LOCATIONS. WE STAND ADJOURNED.

25 (THE MEETING WAS THEN CONCLUDED AT 12:23 P.M.)

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 INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE AND THE APPLICATION REVIEW SUBCOMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING ON AUGUST 25, 2016, 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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