

BEFORE 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: THE WESTIN SAN FRANCISCO AIRPORT
1 OLD BAYSHORE DRIVE
MILLBRAE, CALIFORNIA

DATE: WEDNESDAY, MARCH 16, 2016
9 A.M.

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

BRS FILE NO.: 98393

BARRISTERS' REPORTING SERVICE

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12. 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, CLIN 2: PARTNERING OPPORTUNITY FOR CLINICAL TRIAL STAGE PROJECTS AND TRAN1 - 4: TRANSLATION RESEARCH APPLICATIONS. (HEALTH & SAFETY CODE 125290.30(F) (3) (B) AND (C)).	
13. DISCUSSION OF PERSONNEL [EVALUATION OF CIRM PRESIDENT] (GOVERNMENT CODE SECTION 11126, SUBDIVISION (A); HEALTH & SAFETY CODE SECTION 125290.30(F) (3) (D)).	
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BARRISTERS' REPORTING SERVICE

1 MILLBRAE, CALIFORNIA; WEDNESDAY, MARCH 16, 2016

2 9 A.M.

3

4

CHAIRMAN THOMAS: GOOD MORNING, EVERYBODY.

5

WELCOME TO BEAUTIFUL MILLBRAE FOR THE MARCH 2016

6

EDITION OF THE ICOC BOARD MEETING. MARIA, WILL YOU

7

PLEASE LEAD US IN THE PLEDGE OF ALLEGIANCE.

8

(THE PLEDGE OF ALLEGIANCE.)

9

CHAIRMAN THOMAS: MARIA, WILL YOU PLEASE

10

CALL THE ROLL.

11

MS. BONNEVILLE: LINDA BOXER.

12

DR. BOXER: PRESENT.

13

MS. BONNEVILLE: KEN BURTIS.

14

DR. BURTIS: PRESENT.

15

MS. BONNEVILLE: JACK DIXON.

16

DR. DIXON: HERE.

17

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

18

DR. DULIEGE: PRESENT.

19

MS. BONNEVILLE: HOWARD FEDEROFF.

20

ELIZABETH FINI.

21

DR. FINI: HERE.

22

MS. BONNEVILLE: MICHAEL FRIEDMAN. JUDY

23

GASSON.

24

DR. GASSON: HERE.

25

MS. BONNEVILLE: SAM HAWGOOD. DAVID

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1 HIGGINS.

2 DR. HIGGINS: PRESENT.

3 MS. BONNEVILLE: STEPHEN JUELSGAARD.

4 MR. JUELSGAARD: HERE.

5 MS. BONNEVILLE: SHERRY LANSING. KATHY

6 LAPORTE.

7 DR. LAPORTE: PRESENT.

8 MS. BONNEVILLE: BERT LUBIN.

9 DR. LUBIN: HERE.

10 MS. BONNEVILLE: SHLOMO MELMED.

11 DR. MELMED: HERE.

12 MS. BONNEVILLE: LAUREN MILLER.

13 MS. MILLER: HERE.

14 MS. BONNEVILLE: ADRIANA PADILLA.

15 DR. PADILLA: HERE.

16 MS. BONNEVILLE: JOE PANETTA.

17 MR. PANETTA: HERE.

18 MS. BONNEVILLE: ROBERT PRICE.

19 DR. PRICE: HERE.

20 MS. BONNEVILLE: FRANCISCO PRIETO. ROBERT

21 QUINT. AL ROWLETT.

22 MR. ROWLETT: HERE.

23 MS. BONNEVILLE: JEFF SHEEHY.

24 MR. SHEEHY: HERE.

25 MS. BONNEVILLE: OSWALD STEWARD.

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1 DR. STEWARD: HERE.

2 MS. BONNEVILLE: JONATHAN THOMAS.

3 CHAIRMAN THOMAS: HERE.

4 MS. BONNEVILLE: ART TORRES.

5 MR. TORRES: HERE.

6 MS. BONNEVILLE: CARL WARE.

7 DR. WARE: HERE.

8 MS. BONNEVILLE: DIANE WINOKUR.

9 MS. WINOKUR: HERE.

10 CHAIRMAN THOMAS: THANK YOU, MARIA. WE'LL
11 PROCEED TO THE CHAIR'S REPORT. THE FIRST THING I'D
12 LIKE TO MENTION, WHICH MARIA JUST REFERENCED IN HER
13 ROLL CALL, IS WE HAVE A NEW MEMBER OF THE ICOC WHO
14 WILL BE JOINING US AT OUR NEXT IN-PERSON BOARD
15 MEETING. HE IS DR. HOWARD FEDEROFF WHO IS THE UC
16 IRVINE'S VICE CHANCELLOR FOR HEALTH AFFAIRS AND THE
17 DEAN OF MEDICINE. EVERYBODY WILL ENJOY MEETING HIM.
18 WE WENT DOWN AND BRIEFED HIM ON ALL CIRM MATTERS A
19 NUMBER OF WEEKS AGO, AND HE'S A VERY ENTHUSIASTIC
20 NEW MEMBER, AND WE LOOK FORWARD TO HIS JOINING OUR
21 GROUP.

22 PROCEEDING, SO THERE WERE A NUMBER OF
23 THINGS IN THE LAST THREE MONTHS THAT HAVE HAPPENED
24 OF INTEREST. AS YOU KNOW, IN EARLY JANUARY EVERY
25 YEAR, THE JP MORGAN CONFERENCE CONVENES IN SAN

BARRISTERS' REPORTING SERVICE

1 FRANCISCO AND BRINGS TOGETHER MEMBERS OF THE BIOTECH
2 COMMUNITY, PATIENTS, THE FINANCE COMMUNITY, ETC.
3 AND ONE OF THE THINGS THAT THEY DO AT THE BEGINNING
4 OF THE FOUR-DAY SESSION IS THE ALLIANCE FOR
5 REGENERATIVE MEDICINE DOES A REVIEW AND SORT OF THE
6 STATE OF THE UNION OF REGENERATIVE MEDICINE AS AN
7 INDUSTRY. AND THEY PRODUCE A REPORT, WHICH I'VE
8 CULLED OUT A FEW SLIDES HERE I THOUGHT THE BOARD
9 WOULD FIND OF INTEREST, AND WE WILL SEND TO YOU A
10 LINK TO THE FULL ARM REPORT.

11 BUT IF I COULD DIRECT EVERYBODY'S
12 ATTENTION TO THE SLIDES, I THINK THE THEME OF THIS
13 YEAR'S MEETING, AS IT TENDS TO BE PROGRESSIVELY
14 EVERY YEAR, IS JUST HOW MUCH IS HAPPENING IN THE
15 REGENERATIVE MEDICINE SPACE AND HOW MANY MORE
16 TECHNOLOGIES ARE BEING DEVELOPED AND COMPANIES
17 FORMED.

18 AND IF YOU LOOK AT THIS FIRST SLIDE, YOU
19 WILL SEE THAT THERE ARE A LOT OF COMPANIES OUT
20 THERE, WAY MORE THAN ONE MIGHT EXPECT, AND EVERY
21 YEAR THE NUMBER INCREASES VERY DRAMATICALLY. SO YOU
22 SEE THE FIGURE, 672 COMPANIES WORLDWIDE BROKEN DOWN,
23 AS YOU SEE ON THAT FIGURE 1, SPEAKING TO THE ISSUE
24 THAT IT IS BECOMING MORE AND MORE OF A PROMINENT
25 SECTOR OF THE MEDICAL RESEARCH COMMUNITY.

BARRISTERS' REPORTING SERVICE

1 IF YOU GO TO THE NEXT SLIDE PLEASE, HERE
2 ARE SOME STATS ON JUST EXACTLY HOW MUCH HAS
3 PROGRESSED TO THE CLINICAL TRIAL STAGE. AND YOU CAN
4 SEE HERE ON THIS SLIDE WE NOW HAVE 192 IN PHASE I,
5 UP FROM 133 THE YEAR BEFORE; 376 IN PHASE II, UP
6 FROM 206 THE YEAR BEFORE; 63 IN PHASE III, UP FROM
7 39. SO YOU SEE A DRAMATIC INCREASE LAST YEAR FROM
8 THE YEAR BEFORE THAT. SO THE FIELD CONTINUES TO
9 PROGRESS.

10 NEXT SLIDE PLEASE. ONE OF THE THINGS
11 THAT'S SORT OF NEAR AND DEAR TO CIRM IS THE NOTION
12 OF COLLABORATION WHETHER IT'S ACADEMIA AND INDUSTRY
13 OR INDUSTRY AND INDUSTRY, ETC. AND HERE ARE A FEW
14 EXAMPLES OF SOME KEY COLLABORATIONS THAT HAPPENED
15 OVER THE COURSE OF THE PAST YEAR. AND YOU CAN SEE
16 THAT THESE AFFECT DIFFERENT DISEASES AND CONDITIONS,
17 BUT ARE ALL QUITE BIG-TICKET COLLABORATIONS THAT
18 HOPEFULLY WILL PROVE TO BE FRUITFUL, AND THE
19 RESEARCH AT ISSUE WILL RESULT IN THERAPIES OR CURES.

20 NEXT SLIDE PLEASE. LAST YEAR, AS YOU
21 KNOW, WAS A BIG YEAR FOR IPO'S IN GENERAL. THE SAME
22 WAS TRUE IN THE BIOTECH SPACE, AND THERE WERE SOME
23 QUITE NOTABLE ONES THAT WE HAVE LISTED HERE. THE
24 MARKET WAS, I THINK, BY ANY ACCOUNTS VERY HOT LAST
25 YEAR. OBVIOUSLY THE FIRST QUARTER HAS BEEN ONE

BARRISTERS' REPORTING SERVICE

1 WHERE THE ECONOMY OR THE STOCK MARKET, AT ANY RATE,
2 HAS BEEN SORT OF UP AND DOWN. SO THE MARKET FOR
3 IPO'S HAS LESSENERED AT THE MOMENT; BUT IF THINGS
4 STABILIZE IN THE MARKET, WE WOULD FULLY EXPECT THAT
5 THE PIPELINE OF OTHER COMPANIES LOOKING TO DO IPO'S
6 BEING ROBUST, THAT THERE WILL BE A NUMBER OF OTHERS
7 THIS YEAR, AND THINGS WILL CONTINUE TO MARCH ALONG.

8 NEXT SLIDE PLEASE. HERE WE SEE A TABLE OR
9 SEVERAL BOXES HERE, RATHER, THAT INDICATE JUST HOW
10 MUCH FINANCING WAS DONE IN THE SPACE. AND YOU CAN
11 SEE THAT IT'S A VERY CONSIDERABLE AMOUNT, 10.8
12 BILLION ALL TOLL ACROSS ALL THE DIFFERENT AREAS OF
13 REGENERATIVE MEDICINE. AND YOU CAN SEE BROKEN IT
14 DOWN: 6.8 OF THAT TO GENE AND GENE-MODIFIED CELL
15 THERAPY, CLOSE TO A BILLION IN TISSUE ENGINEERING,
16 AND 7 BILLION IN WHAT WE'LL CALL REGULAR CELL
17 THERAPY. SO A TREMENDOUS AMOUNT OF ACTIVITY IN THE
18 MARKET LAST YEAR ALL TOWARDS GETTING PROGRESSIVELY
19 MORE AND MORE RESEARCH.

20 AMY, I THINK THAT CONCLUDES. I DON'T KNOW
21 IF ANYBODY HAS ANY QUESTIONS. WHAT I WOULD SUGGEST
22 IS TAKE A LOOK AT THE LINK WHEN WE SEND IT OUT. IT
23 GIVES A LOT MORE BACKGROUND ON ALL THESE DIFFERENT
24 CHARTS AND TABLES AND I THINK WILL REINFORCE THE
25 NOTION PRESENTED AT JP MORGAN, THAT THINGS ARE

BARRISTERS' REPORTING SERVICE

1 PROCEEDING MORE THAN APACE IN THE FIELD.

2 ONE OF THE THINGS THAT JP MORGAN DOES IN
3 BRINGING ENTITIES TOGETHER, BECAUSE THE BOARD
4 APPROVED IN DECEMBER THE ACCELERATING THERAPIES
5 PUBLIC PRIVATE PARTNERSHIP OR ATP3, WE'VE HAD A LOT
6 OF STAKEHOLDER MEETINGS SINCE THEN PARTICULARLY
7 TARGETED AT GETTING POTENTIAL PARTIES WHO WOULD BID
8 ON THE ATP3 RFA WHEN IT GOES OUT IN SUMMER. AND SO
9 WE HAD A NUMBER OF MEETINGS THERE WITH
10 REPRESENTATIVES FROM BIG PHARMA. WE'VE SPOKEN WITH
11 BIG BIOTECH, WE'VE SPOKEN WITH REPRESENTATIVES OF
12 THE VENTURE CAPITAL COMMUNITY, AND INDIVIDUAL HIGH
13 NET WORTH BIOTECH ENTREPRENEURS WHO HAVE HAD REAL
14 TRACK RECORDS IN STARTING AND DEVELOPING SIGNIFICANT
15 BIOTECH COMPANIES, ALL TOWARDS LOOKING TO GENERATE
16 INTEREST SO THAT WE ENSURE THAT WE GET VERY HIGH
17 QUALITY APPLICATIONS THAT COME IN WHEN WE GO OUT IN
18 MIDSUMMER FOR THAT. AND SO THERE WERE A BUNCH OF
19 THOSE MEETINGS THAT A NUMBER OF US WENT TO AT THE JP
20 MORGAN CONFERENCE, AND I'LL REFERENCE ANOTHER
21 SETTING IN A SECOND.

22 WE HAD A VERY INTERESTING MEETING OF THE
23 STANDARDS WORKING GROUP ON GENE EDITING WHICH IS, AS
24 YOU KNOW, A VERY HOT TOPIC PARTICULARLY AS IT
25 APPLIES TO EDITS THAT CAN AFFECT THE GERMLINE AND

BARRISTERS' REPORTING SERVICE

1 INHERITANCE. AND GEOFF LOMAX ON OUR TEAM PULLED
2 TOGETHER A FULL-DAY SESSION ON THIS WITH SHERRY
3 LANSING, BERNIE LO, AND JEFF SHEEHY SORT OF
4 PRESIDING OVER THIS. IT WAS A VERY FASCINATING DAY.
5 THIS COMES ON THE HEELS OF A NUMBER OF SUCH SESSIONS
6 CONVENED BY ISSCR, THE NATIONAL ACADEMY OF SCIENCES,
7 ETC. AND AS A RESULT, WE HAD A NUMBER OF
8 RECOMMENDATIONS THAT CAME FROM THAT DAY THAT ARE
9 STILL IN DRAFT FORM BUT WILL BE PRESENTED AS CIRM'S
10 OFFICIAL POSITION ON THE ISSUE.

11 I SHOULD NOTE PARENTHETICALLY AT THE
12 MILKEN GLOBAL CONFERENCE TAKING PLACE THIS MAY
13 WHICH, AS YOU KNOW, IS AN ANNUAL EVENT, BIG DEAL
14 EVENT DOWN IN LOS ANGELES, I'M GOING TO BE
15 MODERATING A PANEL ON THIS TOPIC, WHICH, AS WITH ALL
16 MILKEN PANELS, WILL BE ON THEIR WEBSITE. SO ANYBODY
17 CURIOUS TO SEE WHAT EXPERTS IN THE FIELD HAVE TO SAY
18 ON THIS TOPIC, WOULD INVITE YOU TO CHECK THAT OUT
19 AFTER MAY 4TH WHEN THE SESSION TAKES PLACE.

20 WE HAD ANOTHER SIGNING WITH THE GOVERNMENT
21 OF ISRAEL. THEIR MINISTER OF SCIENCE, WHO IS NEW TO
22 THE POSITION, WAS VERY INTERESTED IN WHAT SORT OF
23 ACTIVITIES ARE GOING ON WITH CIRM. AND AS SUCH, WE
24 GOT TOGETHER, WE HAD AN MOU THAT WAS ENTERED INTO.
25 I EXPLAINED TO HIM. AND IT WAS A VERY NICE EVENT

BARRISTERS' REPORTING SERVICE

1 THAT TOOK PLACE AT CEDARS. DR. MELMED WAS THE
2 MASTER OF CEREMONIES OF THAT, AND WE HAD A GREAT
3 CROWD THERE FOLLOWED BY AN EVENT THAT EVENING AT A
4 PRIVATE RESIDENCE THAT FEATURED MANY PEOPLE FROM THE
5 GOVERNMENT OF ISRAEL AND MANY PEOPLE FROM THE
6 ISRAELI AMERICAN COMMUNITY WHO ARE INTERESTED IN THE
7 SPACE.

8 WE TALKED ABOUT HOW WE'RE NOW IN OUR CIRM
9 2.0 INCARNATION VERY INTERESTED IN ENCOURAGING
10 BEST-IN-CLASS PROJECTS TO APPLY IF THEY CAN
11 ESTABLISH A CALIFORNIA NEXUS FOR THEIR PROJECT.
12 TYPICALLY THAT WOULD INVOLVE HAVING SOME OF THEIR
13 CLINICAL TRIALS RUN IN THE STATE OF CALIFORNIA. AND
14 THE MINISTER OF SCIENCE WAS VERY INTERESTED IN THAT
15 IDEA. AND, IN FACT, OF COURSE, THERE'S SOME
16 TREMENDOUS WORK BEING DONE IN THE REGENERATIVE
17 MEDICINE SPACE IN ISRAEL. AND I THINK THAT WE WILL
18 SEE SOME APPLICATIONS THAT COME FROM THEM UNDER CIRM
19 2.0 AND ARE LOOKING FORWARD TO THAT.

20 WE HAD A MOST INTERESTING TWO DAYS AGAIN
21 ON THE MILKEN THEME. MILKEN HAD ITS -- THE MILKEN
22 INSTITUTE HAD ITS FIRST GLOBAL PUBLIC HEALTH SUMMIT
23 IN WASHINGTON A COUPLE OF WEEKS AGO. I WAS INVITED
24 TO GO BACK TO REPRESENT CIRM AT THAT. AND IN THE
25 COURSE OF THAT MEETING, ALL OF WHICH, AGAIN, IS

BARRISTERS' REPORTING SERVICE

1 ONLINE, AND YOU CAN GO BACK AND CHECK THE PANELS OUT
2 THERE, IT WAS AN OPPORTUNITY TO TALK TO A NUMBER OF
3 SENIOR OFFICIALS FROM MANY OF THE MAJOR BIG PHARMA
4 COMPANIES -- THE CEO'S WERE THERE OR SENIOR VP'S, OR
5 WHATEVER -- TO TALK ABOUT ATP3 AND TO ENCOURAGE THEM
6 TO CONSIDER APPLYING IF THAT IS A FIELD OF INTEREST
7 THAT APPEALS TO THEM AND IS IN LINE WITH THEIR
8 STRATEGIC MISSION AT THIS POINT. AND I BELIEVE
9 ALREADY THAT WE'VE HAD A NUMBER OF CALLS THAT HAVE
10 COME OUT OF THOSE DISCUSSIONS, AND I BELIEVE WE WILL
11 GET SOME APPLICATIONS THAT ARISE FROM THOSE
12 CONVERSATIONS.

13 WE HAD ANOTHER ANNUAL MEETING AT UCLA THEY
14 HAVE EVERY YEAR. IT'S A ONE-DAY STEM CELL SYMPOSIUM
15 HOSTED BY OWEN WITTE AND THE UCLA STEM CELL TEAM
16 THAT I WAS ASKED TO GO SPEAK TO ON BEHALF OF CIRM
17 THAT IS TYPICAL FOR THAT EVENT. FEATURED A NUMBER
18 OF VERY INTERESTING SPEAKERS. EVERY YEAR SOME OF
19 THOSE ARE FUNDED BY US, AND IT'S ALWAYS GOOD TO GET
20 A PROGRESS REPORT ON WHAT THEY ARE DOING.

21 LAST, BUT NOT LEAST, WE CONTINUE TO HAVE A
22 NUMBER OF DISCUSSIONS FURTHER TO OUR TALK IN
23 DECEMBER ABOUT THE NEED TO GENERATE CONTINGENT
24 ADMINISTRATIVE FUNDS IN THE EVENT THAT MONIES ARE
25 NEEDED IN 2020 WHEN WE RUN OUT OF FUNDS TO HANDLE

BARRISTERS' REPORTING SERVICE

1 THE THREE PLUS YEAR WIND-DOWN THAT WE WOULD HAVE IN
2 THAT CASE. AND SO WE'VE HAD A NUMBER OF DISCUSSIONS
3 ALONG THOSE LINES AND WILL BE REPORTING MORE ON THAT
4 TOPIC WHEN WE GET TO OUR JUNE BOARD MEETING.

5 SO THAT CONCLUDES THE CHAIR'S REPORT.
6 I'LL NOW TURN IT OVER TO DR. MILLS FOR THE
7 PRESIDENT'S REPORT.

8 DR. MILLS: THANK YOU VERY MUCH, CHAIRMAN
9 THOMAS, MEMBERS OF THE BOARD. LET'S GET INTO IT.
10 WE HAVE A LITTLE BIT TO TALK ABOUT HERE IN THE
11 PRESIDENT'S REPORT TODAY.

12 THESE ARE THE THINGS THAT I'M GOING TO GO
13 OVER. FIRST, AS I PROMISED ON MY VERY FIRST DAY,
14 THAT I WOULD NEVER GIVE A PRESENTATION WITHOUT
15 REINFORCING THE CIRM MISSION. THEN I'M GOING TO GO
16 AND REFRESH OUR MEMORY ON THE STRATEGIC PLAN BECAUSE
17 THIS IS NOT SOMETHING WE DID TO PUT ON A SHELF AND
18 FORGET ABOUT. THEN I WANT TO TAKE YOU THROUGH
19 BUDGET REVIEW.

20 SO IT'S BEEN A QUARTER SINCE OUR LAST
21 MEETING. I'LL TAKE YOU THROUGH SORT OF FROM A HIGH
22 LEVEL WHAT WE'RE DOING FROM A BUDGET STANDPOINT.
23 THEN I WANT TO TALK A LITTLE BIT ABOUT THE CIRM 2.0
24 MACHINE THAT WE'VE CREATED AND HOW IT'S RUNNING
25 RIGHT NOW BECAUSE MEASURING PERFORMANCE IS REALLY

BARRISTERS' REPORTING SERVICE

1 IMPORTANT FOR US. AND THEN, LASTLY, I'LL JUST END
2 WITH SOME INTERESTING STUFF THAT'S COMING.

3 BUT, FIRST, OUR MISSION, AS WE SHOULD
4 NEVER FORGET, IS TO ACCELERATE STEM CELL TREATMENTS
5 TO PATIENTS WITH UNMET MEDICAL NEEDS. IF WE'RE NOT
6 DOING THIS, WE'RE DOING THE WRONG THING. IT STARTS
7 AND ENDS WITH THE PATIENT, AND WE SHOULD NEVER
8 FORGET THAT.

9 AS I MENTIONED ON DECEMBER 17TH OF LAST
10 YEAR, WE ADOPTED A BRAND-NEW STRATEGIC PLAN FOR
11 CIRM. IT IS ESSENTIAL FOR US AS AN AGENCY AND AS AN
12 ORGANIZATION TO KEEP THAT DIRECTION, WHICH WE HAVE
13 SET AND WHICH YOU SET UNAMBIGUOUSLY, IN FRONT OF US
14 AT ALL TIME SO WE CAN ACTUALLY ACCOMPLISH THE GOALS
15 THAT WE HAVE SET. AS WE SAID EARLIER, THEY ARE
16 AMBITIOUS GOALS. THEY DON'T REQUIRE THE BENDING OF
17 THE TIME SPACE CONTINUUM, BUT THEY ARE AMBITIOUS
18 GOALS FOR US TO ACCOMPLISH. AND WE WILL NOT
19 ACCOMPLISH THEM BY CHANCE. WE WILL ONLY ACCOMPLISH
20 THEM BY DIRECTED ACTION AND KEEPING THEM IN FRONT OF
21 MIND AND TAKING DELIBERATE STEPS TOWARDS THEM.

22 YOU WILL RECALL THERE'S THREE ASPECTS TO
23 OUR STRATEGIC PLAN, A PUSH, PULL, AND LEVEL. PUSH
24 BEING DEVELOPING OPERATIONAL EXCELLENCE WITHIN THE
25 ORGANIZATION, FULLY OPERATIONALIZING CIRM 2.0,

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1 CREATING THESE ACCELERATING AND TRANSLATING CENTERS
2 THAT WE HAVE. PULL, TRYING TO ENGAGE MORE
3 DOWNSTREAM DEMAND SO CIRM ISN'T THE ONLY ONE IN THE
4 FIGHT HERE TRYING TO MOVE THIS BOULDER OVER THE
5 HILL. AND THEN LASTLY, LEVEL, ENGAGE OUR ARMY OF
6 STAKEHOLDERS THAT WE HAVE AND PATIENT ADVOCATES AND
7 OTHERS AND DRIVE RESPONSIBLE REGULATORY REFORM SUCH
8 HAS BEEN DONE IN JAPAN AND IS BEING DONE THROUGHOUT
9 THE EUROPEAN UNION NOW.

10 VERY IMPORTANTLY ARE WHAT WE CALL
11 INTERNALLY THE BIG SIX. AND THESE ARE THE THINGS
12 THAT WE LAID OUT IN THE PLAN THAT WE ARE GOING TO
13 ACCOMPLISH. SO THESE ARE THE ULTIMATE METRICS OF
14 THIS PLAN. THEY ARE, FIRST, WE WANT TO INTRODUCE
15 FROM BEGINNING TO END IN THE PROCESS 50 NEW
16 THERAPEUTIC OR DEVICE CANDIDATES INTO THE PROCESS.
17 SO 50 NEW THINGS COMING IN. WE WANT THE THINGS
18 INTERNALLY TO THEN MOVE DOWN THE TRACK. SO WE WANT
19 TO HAVE WHAT WE CALL PROGRESSION EVENTS OR PROJECTS
20 MOVING FROM ONE STAGE TO THE NEXT. WE WANT THAT TO
21 INCREASE BY 50 PERCENT OVER OUR HISTORICAL AVERAGE.
22 WE INTEND TO WORK WITH FDA AND OTHERS TO ENACT A
23 NEW, MORE EFFICIENT REGULATORY PARADIGM. VERY
24 IMPORTANTLY, WE WANT THE TIME IT TAKES TO GO FROM
25 TRANSLATION, WHICH WAS ABOUT EIGHT YEARS PREVIOUSLY,

BARRISTERS' REPORTING SERVICE

1 WE WANT TO CUT THAT AT LEAST IN HALF. THAT'S THE
2 TIME IT TAKES FOR US TO COME UP, WHEN WE HAVE A
3 CANDIDATE IDENTIFIED, TO WHEN THAT CANDIDATE'S
4 ACTUALLY READY TO ENTER A CLINICAL TRIAL. FOR THE
5 WORLD OUTSIDE OF STEM CELLS, THAT NUMBER IS 3.2
6 YEARS. SO AT EIGHT YEARS WE CERTAINLY HAVE A LONG
7 WAY TO GO TO CATCH UP TO AVERAGE.

8 THEN WE WANT TO -- OBVIOUSLY THE GOAL IS
9 TO ACCELERATE THESE THERAPIES TO PATIENTS. IN ORDER
10 TO DO THAT, THE DOOR YOU HAVE TO GO THROUGH INVOLVES
11 CLINICAL TRIALS. WE'VE SET A VERY AGGRESSIVE GOAL
12 HERE. WE INTEND TO ADD 50 ADDITIONAL CLINICAL
13 TRIALS TO THE CIRM PORTFOLIO OVER THE NEXT FIVE
14 YEARS, BRINGING OUR TOTAL TO 65 AT LEAST. AND THEN
15 LASTLY, IF THESE TRIALS ARE SUCCESSFUL AND THESE
16 PROGRAMS ARE SUCCESSFUL, WE OUGHT TO BE ABLE TO
17 ENGAGE INDUSTRY PARTNERSHIP SUCH THAT THESE PRODUCTS
18 CAN BE TAKEN UP, FINISHED IN THE FINAL STAGES OF
19 DEVELOPMENT, COMMERCIALIZED, AND MADE AVAILABLE TO
20 PATIENTS AROUND THE WORLD.

21 SO THESE ARE THE BIG SIX. WE HAVE NO
22 INTENTION OF CHANGING THEM UNLESS THE BOARD ASKS US
23 TO. BUT IN ORDER FOR US TO ACCOMPLISH THESE THINGS,
24 AS I SAID, IT WON'T HAPPEN IF WE WALK RANDOMLY IN
25 CHANCE OR WE FORGET ABOUT THESE THINGS. THIS

BARRISTERS' REPORTING SERVICE

1 REQUIRES US TO HAVE A VERY STRONG FOCUS AND MAKE
2 VERY DELIBERATE EFFORTS AND WALK AND ACTUALLY RUN IN
3 THE DIRECTION OF THESE.

4 OKAY. SO THAT'S JUST REFRESHING US ON THE
5 STRATEGIC PLAN.

6 NEXT I WANT TO TALK A LITTLE BIT ABOUT THE
7 BUDGET, AND IT'S NOT ALWAYS THE MOST FUN TOPIC TO
8 TALK ABOUT, BUT I'LL DO MY BEST TO MAKE IT THAT WAY.

9 SO AS YOU WILL RECALL, WE HAVE TWO
10 BUCKETS. WE HAVE THE AWARD BUCKET, AND THAT'S THE
11 BUCKET WHERE ALL OF THE FUNDING WHERE WE DECIDE TO
12 MAKE FUNDING DECISIONS COME OUT OF. IT IS BY FAR
13 THE BIGGER OF THE TWO BUCKETS, 2.75 BILLION WHEN
14 CIRM WAS ORIGINALLY STARTED. AND THEN WE HAVE THE
15 ADMINISTRATIVE BUCKET. THAT'S THE BUCKET WHERE WE
16 PAY FOR ALL OF CIRM'S INTERNAL FUNCTIONS.

17 IF CIRM WERE A CARGO PLANE GOING AROUND
18 AND DELIVERING GRANTS AND RESOURCES TO PEOPLE AROUND
19 THE STATE, THE WAY YOU COULD THINK OF IT IS THE BIG
20 BUCKET IS THE CARGO WE HOLD. THE LITTLE BUCKET IS
21 THE GAS WE HAVE IN THE PLANE. SO WHEN EITHER ONE OF
22 THOSE BUCKETS GOES TO ZERO, CIRM ISN'T OPERATING AS
23 IT OTHERWISE SHOULD. SO IT REQUIRES US TO KNOW
24 WHERE THESE TWO BUCKETS ARE AT ALL TIME.

25 WITH REGARDS TO THE LITTLE BUCKET OR THE

BARRISTERS' REPORTING SERVICE

1 ADMINISTRATIVE BUCKET, WE HAVE SPENT 109 OUT OF A
2 FIXED \$180 MILLION. IT GIVES US \$71 MILLION LEFT.
3 GIVEN OUR PLAN, THIS WILL TAKE US THROUGH 2020. SO
4 THIS IS ON TRACK, BUT IT IS VERY IMPORTANT THAT WE
5 STAY ALWAYS COGNIZANT OF THIS AND REMAIN VERY
6 FISCALLY RESPONSIBLE BECAUSE WE DON'T WANT TO RUN
7 OUT OF GAS BEFORE WE RUN OUT OF AWARDS TO GIVE OUT.

8 WITH REGARDS TO THE BIG BUCKET, WE HAVE
9 AWARDED JUST UNDER \$2 BILLION IN THIS. WE HAVE 761
10 MILLION THAT IS CURRENTLY UNCOMMITTED IN THIS.
11 GIVEN OUR STRATEGIC PLAN, THAT EASILY GETS US TO
12 2020 WITH A PLANNED NET COMMITMENT RATE ON AVERAGE
13 OF 170 MILLION PER YEAR. OUT OF THIS WE THINK WE'RE
14 DOING, AND I'LL TALK MORE ABOUT THIS COMING UP, WE
15 THINK WE'RE DOING PRETTY WELL, AND ACTUALLY WE THINK
16 WE'RE GOING TO DO JUST FINE ON THE COMMITMENT SIDE
17 OF THIS EQUATION.

18 ONE OF THE THINGS WE DIDN'T ANTICIPATE IS,
19 AS WE ENTERED INTO MILESTONE CONTRACTS AND WE BECAME
20 MORE DISCIPLINED ABOUT WHEN PROGRAMS FAILED
21 OBJECTIVELY AND THEY HIT NO-GO MILESTONES,
22 RECOVERING THOSE AWARDS. WE FORECAST ABOUT A
23 10-PERCENT RECOVERY RATE OUT OF THAT. AND AS YOU
24 WILL SEE IN THE NEXT SLIDE, IT'S NOT. OUR RECOVERY
25 RATE IS, DEPENDING ON WHICH KIND OF AWARDS YOU'RE

BARRISTERS' REPORTING SERVICE

1 LOOKING AT, IT'S SOMEWHERE BETWEEN 25 TO 40 PERCENT,
2 WHICH IS THE RIGHT THING TO DO, BUT IT CHANGES SOME
3 OF THE MATH THAT WE HAVE.

4 SO THIS IS HOW OUR AWARD ACTIVITY MOVED
5 AROUND IN THE FIRST HALF. OUR FISCAL YEAR, BY THE
6 WAY, IS ON A JULY TO JUNE BASIS. SO THIS IS HOW THE
7 MONEY MOVED AROUND IN OUR FIRST TWO MONTHS WHICH
8 WOULD HAVE ENDED IN DECEMBER.

9 OUR UNCOMMITTED BUCKET FELL BY \$14 MILLION
10 ON NET BECAUSE WE MADE \$38 MILLION IN NEW AWARDS.
11 THAT UNCOMMITTED BUCKET WAS OFFSET BY \$23 MILLION IN
12 RECAPTURE AND REPAYMENTS, EITHER THROUGH WHEN AN
13 AWARD FAILED AND IT WAS CANCELED AND THE MONEY
14 BECOMES UNCOMMITTED AGAIN OR THERE ARE AT TIMES
15 AWARD REPAYMENTS WHEN WE OVERPAID FOR AN AWARD AND
16 FOUND AT THE END OF THE AWARD THERE WAS MONEY LEFT
17 OVER. WE GO BACK AND RECLAIM THAT MONEY. AND SO
18 ALTHOUGH WE MADE \$38 MILLION OF AWARDS IN THE FIRST
19 HALF OF THE YEAR, OUR NET COMMITMENT WAS ONLY 15
20 MILLION BECAUSE WE HAD SUCH HIGH RATES OF RECLAIMING
21 CANCELED OR REDUCED AWARDS.

22 NOW, THIS IS A LITTLE -- THIS WOULD PAINT
23 A SLIGHTLY LOW PICTURE OF HOW THE PROGRAM IS
24 ACTUALLY RUNNING BECAUSE DURING THE FIRST FISCAL
25 HALF OF THE YEAR, WE WERE JUST STARTING UP OUR NEW

BARRISTERS' REPORTING SERVICE

1 PROGRAMS. WHEN WE LOOK AT HOW THOSE ARE DOING NOW,
2 IF WE JUST PROJECTED THROUGH BASICALLY THE NEXT 15
3 DAYS, AND OBVIOUSLY ALL CONTINGENT UPON THE BOARD'S
4 DECISIONS, THIS IS WHAT IT LOOKS LIKE THROUGH THREE
5 QUARTERS. SO THE NET COMMITMENT RATES ARE STARTING
6 TO COME UP DRAMATICALLY. OUR AWARD RATE GOES FROM
7 38 TO 128 MILLION. OUR RECOVERY RATES ARE STILL
8 PRETTY HIGH. WE'RE AT 44 MILLION COMBINED PROJECTED
9 IN RECOVERY RATES THROUGH THE THREE QUARTERS OF THIS
10 YEAR.

11 AGAIN, THAT'S JUST WHAT RESPONSIBILITY
12 LOOKS LIKE IN OUR INSTITUTION AND OUR AGENCY. WE
13 HAVE A FISCAL RESPONSIBILITY TO MAKE SURE THAT WHEN
14 WE SAY WE'RE GOING TO SPEND MONEY ON A PROGRAM, THAT
15 THAT MONEY GETS SPENT ON THAT PROGRAM. AND IF THE
16 PROGRAM DOESN'T WORK, THEN THAT MONEY HAS GOT TO
17 COME BACK TO CIRM SO IT CAN HELP SOMEONE ELSE.

18 SO THAT'S THE REAL QUICK BUDGET REVIEW.
19 OBVIOUSLY I'LL TAKE QUESTIONS ON ALL OF THIS AT THE
20 END; OR IF YOU WANT TO INTERRUPT ME, FEEL FREE TO.

21 THE NEXT THING I WANT TO TALK ABOUT IS
22 THIS, AND THIS IS DIFFICULT TO SEE AND IT'S HARD,
23 BUT THIS IS ONE OF THE COOLEST THINGS THERE ARE.
24 THIS IS NOW FULLY INTACT, THE CIRM 2.0 MACHINE WHICH
25 THE TEAM AND THE BOARD AND THE STAKEHOLDERS SPENT

BARRISTERS' REPORTING SERVICE

1 ALL OF LAST YEAR BUILDING FROM THE EARLIEST
2 DISCOVERY AWARDS THROUGH TRANSLATION THROUGH
3 CLINICAL. IT IS NOW ALL UP AND RUNNING.

4 AND NOW WHEN WE TALKED -- NOW IT'S ALMOST
5 A YEAR AND A HALF AGO WE TALKED ABOUT LAYING OUT
6 TRAIN TRACK TO GO FROM ONE SIDE OF THIS TO THE
7 OTHER. THIS IS THE ACTUAL TRAIN TRACK. YOU CAN GO
8 FROM OUR WE CALL IT DISC1 INCEPTION AWARD. YOU CAN
9 GO FROM THE EARLIEST SEED GRANT WE CAN HAVE THAT
10 FUNDS A LOT OF SMALL, NEW, INNOVATIVE IDEAS INTO
11 DISC2, QUEST AWARD, LARGER MONEY FOR BIG, BOLD
12 RESEARCH IDEAS. GET A CONCEPT WORKED OUT, GO
13 SEAMLESSLY INTO TRANS1, 2, OR 3 OR 4, WHICH ARE THE
14 TRANSLATIONAL ACTIVITIES YOU NEED TO GET TO THE
15 STAGE WHERE YOU ARE READY TO HAVE A PRE-IND MEETING
16 AND ACTUALLY START TALKING TO THE FDA ABOUT CLINICAL
17 TRIALS. GO SEAMLESSLY FROM THERE WITHOUT WASTING
18 ANY TIME INTO CLIN1, WHICH GETS YOU YOUR IND. AND
19 FROM CLIN1 DIRECTLY INTO CLIN2, WHICH IS WHERE YOUR
20 CLINICAL TRIALS ACTUALLY GET RUN.

21 AND SO THIS WHOLE THING NOW EXISTS
22 BEGINNING TO END, SEAMLESS, LOCKED TOGETHER. SO WE
23 CAN, I THINK, AS AN AGENCY WE SHOULD BE VERY PROUD
24 OF THIS. I THINK IT'S AN EXTRAORDINARY
25 ACCOMPLISHMENT. AND IT'S UP AND RUNNING RIGHT NOW.

BARRISTERS' REPORTING SERVICE

1 SO LOOKING AT JUST HOW IT'S PERFORMING, IF
2 YOU GO TO THOSE THREE BUCKETS, DISCOVERY,
3 TRANSLATION, AND CLINICAL, ONE OF THE WAYS WE CAN
4 MEASURE PERFORMANCE, AT LEAST INITIALLY EARLY ON, IS
5 SIMPLY ARE WE FUNDING PROGRAMS IN ANY OF THESE. SO
6 THE DISCOVERY ASPECT IS JUST COMING ONLINE RIGHT
7 NOW. WE HAVE TWO SETS OF APPLICATIONS THAT WE HAVE
8 IN THE AGENCY, INCEPTION, WHICH IS THAT SEED AWARD,
9 AND QUEST, WHICH IS THE LARGER, THE LARGER DISCOVERY
10 AWARD. BETWEEN THOSE TWO WE'VE RECEIVED 180
11 APPLICATIONS ON OUR FIRST APPLICATION CYCLE. SO
12 THAT'S FANTASTIC. OUR FORECAST FULLY UP AND RUNNING
13 RUN RATE FOR DISCOVERY WOULD BE ABOUT \$50 MILLION A
14 YEAR. WE'RE GOING TO DO THAT EASILY.

15 WHEN YOU LOOK IN TRANSLATION, WE'RE
16 PROJECTED TO AWARD 37 MILLION IN TRANSLATION. THIS
17 IS AN AWARD WHICH IS GIVEN TWICE A YEAR. ACTUALLY
18 OUR FULL YEAR UP AND RUNNING FORECASTS 45. SO IN
19 ONE ROUND WE'RE DOING 37. THE ONLY DANGER WE HAVE
20 HERE IS WE'RE EXCEEDING OUR RUN RATE ON THAT.

21 AND THEN LASTLY, CLINICAL. WE ARE AT 71
22 MILLION IN CLINICAL, WHICH IS AGAINST A FORECAST RUN
23 RATE OF HUNDRED MILLION WHEN WE'RE UP FULLY AT
24 SPEED. SO WE'RE WELL, WELL ON OUR WAY TO HAVING ALL
25 THREE OF THESE PARAMETERS UP AND RUNNING THE WAY WE

BARRISTERS' REPORTING SERVICE

1 SHOULD.

2 TALK A LITTLE BIT MORE ABOUT THE
3 PERFORMANCE OF THE AGENCY AND NOW DIGGING INTO
4 CLINICAL BECAUSE IT'S THE ONE WE HAVE THE MOST DATA
5 ON. SINCE WE STARTED THE 2.0 PROGRAM, WHICH IS NOW
6 12 MONTHS OLD OFFICIALLY, WE'VE RECEIVED 36
7 APPLICATIONS, 25 OF WHICH HAVE PASSED ELIGIBILITY.
8 KEEP IN MIND ONE OF THE THINGS WE DO NOW BEFORE WE
9 LET AN APPLICATION GO ON TO THE GRANTS WORKING GROUP
10 IS WE MAKE SURE IT PASSES A BUDGET REVIEW. AND WE
11 TAKE THAT BUDGET REVIEW SERIOUSLY BECAUSE WE DON'T
12 WANT TO HAVE FLUFF IN OUR BUDGETS. WE WANT TO MAKE
13 SURE THAT WHEN WE PUT A BUDGET BEFORE THE GRANTS
14 WORKING GROUP AND BEFORE THE ICOC, THAT WHAT WE'RE
15 BUYING IS APPROPRIATE FOR HOW MUCH WE'RE SPENDING.

16 TWENTY-FIVE OF THE 36 PASSED ELIGIBILITY;
17 20 APPLICATIONS HAVE BEEN FULLY ADJUDICATED BY THE
18 GRANTS WORKING GROUP. THERE ARE FIVE THAT ARE STILL
19 UNDER REVIEW; BUT OUT OF THE 20 THAT HAVE BEEN FULLY
20 ADJUDICATED, WE HAVE FUNDED NINE OF THEM OR WE HAVE
21 RECOMMENDED FOR FUNDING FOR NINE. SO IT'S 45
22 PERCENT. I KNOW WE WENT THROUGH A PATCH, AND DIANE
23 CORRECTLY RAISED SOME QUESTIONS ABOUT IT WHERE IT
24 SEEMED LIKE WE WERE IN A BIT OF A DESERT. BUT
25 THROUGH 20 FULLY DISPOSED APPLICATIONS, TO HAVE

BARRISTERS' REPORTING SERVICE

1 FUNDING FOR 45 PERCENT OF THEM IS ACTUALLY A VERY,
2 VERY HIGH FUNDING PERCENTAGE.

3 REALLY CRITICAL FOR US IN THIS AND
4 EVERYTHING WE DO, PARTICULARLY WHEN WE HAVE GOALS
5 LIKE GOING OUT AND GETTING 50 NEW CLINICAL TRIALS,
6 IS THAT UNDER NO CIRCUMSTANCES DO WE EVER LOWER THE
7 QUALITY OF WHAT WE DO BECAUSE WHEN WE LOWER THE
8 QUALITY OF WHAT WE DO, WE DON'T HELP ANY OF OUR
9 PATIENTS, AND THE PATIENT IS THE NO. 1 THING.

10 LOOKING A LITTLE BIT MORE INTO OUR
11 PORTFOLIO, THIS IS THE CLINICAL TRIAL PORTFOLIO THAT
12 WE HAVE. AGAIN, IT PRESUMES AN ICOC FAVORABLE
13 DECISION TODAY ON A DUCHENNE'S MUSCULAR DYSTROPHY
14 PROGRAM. BUT WE HAVE FUNDED 16 TRIALS. WE HAVE 15
15 ACTIVE NOW, AND THIS IS SOMETHING THAT'S GOING TO
16 HAPPEN AS WE GO ON. IF WE LOOK INTO THAT PORTFOLIO
17 JUST A LITTLE BIT MORE, AND YOU CAN BREAK IT UP INTO
18 THREE GROUPS, IN NEURO-OCULAR WE HAVE SIX CLINICAL
19 STAGE PROGRAMS, THREE IN NEUROLOGICAL DISEASE OR
20 INJURY, THREE IN OCULAR. IN BLOOD AND CANCER WE
21 HAVE 15. FIVE ARE FOR BLOOD DISORDERS, THREE ARE
22 FOR HIV OR AIDS, AND SEVEN ARE FOR CANCER.

23 THE ASTERISKS ON THE ONE FOR SEVEN IN
24 CANCER, AND THIS IS SOMETHING WE SAID WE WERE GOING
25 TO START DOING IS WE'RE GOING TO START UPDATING THE

BARRISTERS' REPORTING SERVICE

1 BOARD ON MATERIAL CHANGES. IN CANCER WE
2 UNFORTUNATELY THIS QUARTER HAD A CLINICAL TRIAL
3 TERMINATE. WE HAD SADLY A PHASE III REFRACTORY
4 MELANOMA, METASTATIC MELANOMA TRIAL THAT WAS
5 TERMINATED BECAUSE IT BELIEVED IT WOULD NOT BE ABLE
6 TO HIT ITS ENDPOINT. SO THAT CANCER NUMBER IS
7 ACTUALLY GOING TO GO FROM SEVEN TO SIX. THAT'S OUR
8 ONLY MATERIAL EVENT ON THIS PORTFOLIO THIS QUARTER.

9 WITHIN ORGAN SYSTEMS, WE HAVE FIVE, TWO
10 CARDIOVASCULAR, TWO FOR DIABETES, AND ONE PULMONARY
11 AIRWAY APPLICATION.

12 SO WHAT WE HAD TALKED ABOUT DOING AND WHAT
13 WE'RE GOING TO TRY TO DO TODAY IS I WILL ON A
14 RECURRING BASIS GO THROUGH AND UPDATE THE BOARD ON
15 THESE SORT OF MATERIAL EVENTS THAT HAPPEN, AND THEN
16 LATER ON RAMONA DOYLE, DR. DOYLE AND HER TEAM ARE
17 GOING TO GIVE A SPOTLIGHT ON A PARTICULAR GROUP OF
18 DISEASES THAT WE'RE TREATING. SO TODAY WE'RE GOING
19 TO DO OUR OCULAR DISEASES. AND SO SHE'LL ACTUALLY
20 GIVE YOU AN IN-DEPTH PORTFOLIO UPDATE ON OUR OCULAR
21 PROGRAMS. AND WE'LL JUST FROM MEETING TO MEETING
22 WORK OUR WAY THROUGH OUR PORTFOLIO AND KEEP DOING
23 IT. THAT WAY YOU GUYS CAN STAY REFRESHED ON THE
24 PORTFOLIO WITHOUT HAVING TO HAVE US SPEND SEVEN
25 HOURS A MEETING GOING THROUGH THE ENTIRE THING.

BARRISTERS' REPORTING SERVICE

1 WE'RE TESTING IT. SO IF THERE'S SOMETHING ABOUT IT
2 YOU DON'T LIKE OR THERE'S SOMETHING ABOUT IT YOU
3 THINK WE CAN MAKE BETTER, LET US KNOW. WE WOULD
4 LOVE TO HEAR THAT. WE'RE TRYING TO GET THE PRODUCT
5 OBVIOUSLY AS GOOD AS WE POSSIBLY CAN SO YOU GUYS CAN
6 BE AS INFORMED AS POSSIBLE.

7 THEN LASTLY, JUST WHAT TO EXPECT COMING
8 UP. WE ARE GOING TO MAKE A RECOMMENDATION TO THE
9 BOARD NEXT BOARD MEETING, NOT THIS BOARD MEETING, TO
10 REVISE OUR CLINICAL STAGE SCORING SYSTEM. THIS IS
11 ONLY THE CLINICAL STAGE, SO CLIN1, CLIN2, OR CLIN3,
12 WHERE THE GWG MEETS EVERY SINGLE MONTH. IN THAT
13 PROGRAM WE HAVE A SCORING SYSTEM OF 1, 2, OR 3. AND
14 THE 1 IS IT'S MERITORIOUS AS IS, YOU GUYS SHOULD
15 FUND IT. TWO IS IT'S NOT QUITE THERE, BUT WE THINK
16 IT COULD BE THERE IF IT HAD SOME THINGS FIXED.
17 LET'S SEE IF WE CAN GET IT FIXED, RESUBMITTED, AND
18 HOPEFULLY FIXED SO IT CAN BUMP UP TO A 1 AND
19 ULTIMATELY GO ON AND GET FUNDED.

20 THE 2 SYSTEM HAS BEEN VERY, VERY EFFECTIVE
21 IN CIRM 2.0. WE'VE HAD A NUMBER OF APPLICATIONS
22 THAT HAVE BEEN MADE MATERIALLY BETTER BY SPENDING
23 SOME TIME IN THE 2 BOX WHERE THEY ACTUALLY REVISED
24 THEIR APPLICATIONS AND CAME BACK WITH A MUCH, MUCH
25 STRONGER PRODUCT. AGAIN, OUR GOAL HERE ISN'T TO SEE

BARRISTERS' REPORTING SERVICE

1 IF WE CAN GET AS MUCH THROUGH AS FAST AS WE CAN. WE
2 WANT TO GET AS MUCH THROUGH AS FAST AS WE CAN WITH
3 AS HIGH A QUALITY AS WE POSSIBLY CAN. AND SO WE
4 WANT 95S, NOT 75S.

5 MR. PANETTA: THANKS, RANDY. IS THERE ANY
6 CORRELATION BETWEEN THOSE THREE SCORES, 1, 2, AND 3,
7 AND THE CURRENT SCORING SYSTEM?

8 DR. MILLS: I'M SORRY. THIS IS THE
9 CURRENT SCORING SYSTEM RIGHT NOW. I HAVEN'T GOTTEN
10 TO THE PUNCHLINE OF WHAT WE WANT TO CHANGE.

11 THE CHANGE IS ACTUALLY INCREDIBLY MINOR,
12 BUT IT DEALS WITH NO. 3. I DESCRIBED NO. 1 AND NO.
13 2. NO. 3 IS THE PROGRAM IS SO FLAWED, WE DON'T WANT
14 TO SEE IT AGAIN. THIS IS THE DEATH PENALTY OR THE
15 LIFETIME BAN OR WHATEVER YOU WANT TO CALL IT. THIS
16 SHOULD NOT BE RESUBMITTED. WE DON'T ALLOW THESE
17 PROGRAMS AS IS TO BE RESUBMITTED.

18 THE REASON A 3 EXISTS AT ALL IS BECAUSE WE
19 WERE WORRIED ABOUT NUISANCE APPLICATIONS WHERE
20 SOMEBODY IS JUST APPLYING AND APPLYING AND APPLYING.
21 WE COULD END UP WEARING DOWN THE GWG.

22 OUR REVIEW TEAM THINKS A LOT AND THEY
23 THINK ABOUT FAIRNESS AND THEY THINK ABOUT HOW WE CAN
24 ACTUALLY HAVE THINGS THE BEST AND HOW THE SYSTEM IS
25 WORKING. AND WHAT WE THOUGHT WAS THAT THE

BARRISTERS' REPORTING SERVICE

1 LIKELIHOOD THAT SOMEBODY WOULD LOB IN NUISANCE
2 APPLICATIONS IS PROBABLY NOT WORTH THE UNINTENDED
3 CONSEQUENCES OF PUTTING A LIFETIME BAN ON SOMETHING
4 THAT ACTUALLY COULD BE FIXED AND COME BACK IN. SO
5 WE COULD HAVE A SITUATION WHERE WE PUT A 3 ON
6 SOMETHING; BUT IF YOU READ THE COMMENTS ABOUT THE 3,
7 IT'S LIKE, WELL, IF THEY HAVE THIS DATA AND THEY HAD
8 THIS DATA AND THIS DATA, I WOULD ACTUALLY PROBABLY
9 CONSIDER IT. BUT THAT WOULD TAKE A LONG TIME.

10 SO WHAT WE SAID WAS WE CAN JUST MAKE A
11 SLIGHT MODIFICATION TO THIS, AND THIS IS WHAT WE'RE
12 GOING TO PROPOSE NEXT MONTH, IS THAT THE BAN NOT BE
13 LIFETIME, THAT THE BAN BE SIX MONTHS. AND BASICALLY
14 SAY, LOOK, YOU GUYS, YOU HAVE A GRANT THAT HAS A
15 PROBLEM. DON'T THINK YOU CAN JUST THROW IT BACK IN
16 NEXT MONTH AND EVERYTHING IS GOING TO BE OKAY. YOU
17 NEED TO GET NEW DATA OR YOU NEED TO HAVE A MEETING
18 WITH THE FDA OR SOMETHING. BUT WE'RE NOT GOING TO
19 ERR ON THE SIDE OF GIVING YOU THE DEATH PENALTY WHEN
20 IT'S POSSIBLE THAT THE APPLICATION CAN ACTUALLY BE
21 FIXED.

22 WHAT I LIKED ABOUT IT WAS THE REVIEW TEAM
23 SAID, YOU KNOW WHAT, WE'LL DEAL WITH THE
24 CONSEQUENCES OF IF SOMEBODY ABUSES US AND WE HAVE TO
25 DEAL WITH A NUISANCE APPLICATION EVERY SIX MONTHS.

BARRISTERS' REPORTING SERVICE

1 THEN WE'LL DEAL WITH THE NUISANCE APPLICATION, BUT
2 WE'D RATHER ERR ON THE SIDE OF NOT REJECTING A GOOD
3 THING THAN INADVERTENTLY REJECTING A GOOD THING SO
4 WE DIDN'T HAVE TO DO LESS WORK. SO THIS IS THE
5 PROPOSAL THAT WE HAVE.

6 DR. STEWARD: RANDY, I JUST WANTED TO ASK
7 YOU TO MAYBE UNPACK A LITTLE BIT MORE ABOUT NO. 2
8 BECAUSE IT SEEMS TO ME THAT EMBEDDED IN THAT IS ALSO
9 THE ASSUMPTION THAT THERE MIGHT BE GRANTS THAT COME
10 IN, GET A 2, COME BACK, STILL GET A 2, AND, IN FACT,
11 THEY MIGHT DO THAT SEVERAL TIMES. IN FACT, THE
12 SCORE CHANGES THAT THEY NEED TO MAKE ON IT MIGHT
13 TAKE SIX MONTHS TO A YEAR. I JUST WANTED TO SORT OF
14 UNPACK THAT A LITTLE BIT BECAUSE IT DOESN'T MEAN
15 THAT A 2 COMES BACK IN THE NEXT MONTH AND GETS
16 FUNDED.

17 DR. MILLS: ABSOLUTELY NOT. TWOS COME
18 BACK AND GO TO 3S AS OFTEN AS THEY COME BACK AND
19 THEY GO TO 1S. SO A 2 MIGHT MEAN WE WANT MORE
20 INFORMATION ABOUT THIS. WE'RE GOING TO GIVE YOU
21 ADVICE ON HOW TO MAKE THIS BETTER. ONCE WE GET MORE
22 INFORMATION ABOUT THAT APPLICATION, IT MIGHT MAKE IT
23 CLEAR IT'S NOT A 1, IT'S A 3. TWO IS A SORT OF
24 PATHWAY TO SORT OF FIGURE OUT WHETHER OR NOT IT
25 SHOULD MOVE UP MERITORIOUSLY AND WE CAN MAKE IT

BARRISTERS' REPORTING SERVICE

1 BETTER OR WE SHOULD MOVE IT DOWN.

2 THE PROBLEM WE HAD SORT OF WITH THE 2 AND
3 THE 3 HERE, AND THIS IS REALLY WHERE THE ISSUE IS,
4 IS WHAT DO YOU DO WITH A GRANT WHERE THE AMOUNT OF
5 REWORK IT NEEDS REQUIRES 12 MONTHS OF WORK. IT SITS
6 BEFORE THE GWG AS A 2 OVER AND OVER AND OVER AGAIN
7 WHEN WE KNOW AND THE APPLICANT KNOWS IT'S GOING TO
8 TAKE A YEAR TO GET THIS THING FIXED. WE SOMETIMES
9 GIVE THOSE A 3 WHEN UNDER THE OLD SYSTEM WE REALLY
10 SHOULDN'T HAVE; BUT ON THE OTHER HAND, IT DOESN'T
11 REALLY FEEL LIKE A 2 IS THE APPROPRIATE PLACE FOR
12 IT. SO IF WE JUST PULL THE LIFETIME BAN OFF OF 3
13 AND SAY, FOR SOMETHING THAT NEEDS AT LEAST SIX
14 MONTHS WORTH OF WORK, WE CAN DEAL WITH THE ORIGINAL
15 PROBLEM, WHICH IS NUISANCE APPLICATIONS, AND WE
16 NEVER HAVE TO WORRY ABOUT ACCIDENTALLY SENDING
17 SOMETHING TO DEATH THAT SHOULD AND COULD BE SAVED.
18 DOES THAT MAKE SENSE?

19 SO THEN I'LL JUST PROMISE, LAST SLIDE,
20 WHICH IS WHAT'S COMING UP NEXT, BECAUSE NOW THAT
21 WE'VE STARTED THIS ENGINE, THIS CIRM 2.0 ENGINE, WE
22 HAVE A LOT OF REALLY, REALLY NEAT STUFF COMING UP.
23 SO INCEPTION AWARD, THIS IS OUR SEED AWARD. WE'RE
24 DOING A REVIEW FOR THIS, OUR FIRST REVIEW, IN APRIL
25 COMING UP. ACCELERATING CENTER, THIS IS OUR CRO

BARRISTERS' REPORTING SERVICE

1 THAT WE'RE GOING TO BE STARTING SPECIFICALLY IN
2 CALIFORNIA FOR STEM CELLS. THAT REVIEW IS GOING TO
3 COME UP IN MAY. WE'VE HAD VERY GOOD INTEREST FOR
4 THAT. FOLLOW THAT WITH QUEST AND CHALLENGE AWARDS.
5 THESE ARE OUR LARGER DISCOVERY PHASE AWARDS. THE
6 CHALLENGE IS WHERE WE HAVE A SPECIFIC QUESTION THAT
7 WE'RE ASKING AND WE WANT ANSWERED. THE QUEST IS
8 OPEN MIC NIGHT. YOU BRING TO US THE BEST IDEAS YOU
9 HAVE AND WE EVALUATE THEM. THOSE ARE COMING IN
10 JUNE. RIGHT AFTER THAT IN OCTOBER, TRANSLATING
11 CENTER. SO THIS IS WHERE WE'RE ACTUALLY DOING THE
12 IND-ENABLING RESEARCH. AND LASTLY, TRANSLATION
13 GRANT AWARD, WHICH BRINGS US FULL CIRCLE BACK TO
14 TODAY WHICH WE'RE REVIEWING THE TRANSLATION AWARDS
15 FOR. AND THEN THIS CYCLE JUST CONTINUES OVER AND
16 OVER AND OVER AGAIN. OBVIOUSLY WITH EVERY MONTH
17 THERE BEING CLINICAL GWG MEETINGS AND PROGRAM
18 REVIEWS.

19 THAT'S JUST A LOOK AT WHAT'S TO COME. I
20 WILL SHUT UP UNLESS Y'ALL HAVE QUESTIONS FOR ME.

21 DR. DIXON: I HAVE A QUESTION. THIS IS
22 JACK DIXON. RANDY, I THINK MAYBE IT WAS CHAIRMAN
23 THOMAS BROUGHT UP THE CONCEPT THAT A CERTAIN AMOUNT
24 OF MONEY WAS SORT OF RECYCLED IN THINGS THAT DIDN'T
25 WORK OR MILESTONES THAT WEREN'T MET, ETC. WHAT

BARRISTERS' REPORTING SERVICE

1 PERCENTAGE OF THE ADMINISTRATIVE EFFORT BASICALLY
2 GOES INTO THAT PROCESS? ANY THOUGHT ABOUT THAT?

3 DR. MILLS: OH, A LOT OF THOUGHT ABOUT IT.
4 SO I BELIEVE THE QUESTION CENTERS AROUND WHEN WE --
5 SO LET ME JUST GIVE YOU THE CLINICAL TRIAL BLOW-UP
6 THAT WE HAD. THAT WAS ABOUT A \$20 MILLION AWARD. I
7 THINK WE AND THEY HAD SPENT \$3 MILLION EACH ON THAT.
8 SO WHEN THEY STOPPED THAT CLINICAL TRIAL, WE WERE
9 LEFT WITH \$17 MILLION WHICH THEY DIDN'T SPEND AND
10 WEREN'T GOING TO SPEND. SO WE RECAPTURED. THAT'S
11 \$17 MILLION THAT UNDER THE AWARD COMES BACK TO CIRM
12 BECAUSE THE COMPANY DOESN'T GET TO KEEP IT. SO THAT
13 COMES BACK TO CIRM AND IT GOES INTO AN UNCOMMITTED
14 BUDGET.

15 SO WE ARE UNCOMMITTED -- BASICALLY THE
16 AWARD BUCKET GOES UP BY \$17 MILLION. THE PROBLEM WE
17 HAVE IS THAT THE LITTLE BUCKET DOESN'T. THE LITTLE
18 BUCKET IS A UNIDIRECTIONAL BUCKET. IT ONLY GOES
19 DOWN AND WE DON'T HAVE A WAY OF ACTUALLY RECHARGING
20 THAT.

21 AND SO THE ORIGINAL CONCEPT OF PROPOSITION
22 71 SAID 6 PERCENT -- WE'RE GOING TO USE 6 PERCENT OF
23 THE AWARD BASICALLY OF THE 3 BILLION, THE AWARD
24 BUCKET, TAKE OUT THE DEBT SERVICE, 6 PERCENT OF THAT
25 WAS GOING TO BE USED FOR ADMINISTRATIVE COSTS. BUT

BARRISTERS' REPORTING SERVICE

1 IT DIDN'T REALLY CONTEMPLATE WHAT HAPPENED IF WE
2 WERE DOING A REALLY GOOD JOB AND BEING GOOD STEWARDS
3 OF THAT MONEY AND RECAPTURING MONEY WHEN A TRIAL
4 FAILED.

5 SO WE HAVE TO INCUR READMINISTRATION COSTS
6 ASSOCIATED WITH THAT, BUT WE DON'T GET AN ADDITIONAL
7 6 PERCENT MORE TO DO THAT WITH, WHICH IS WHY I PUT
8 ON THE LITTLE BUCKET SLIDE FISCAL RESPONSIBILITY
9 HERE AS REALLY, REALLY IMPORTANT BECAUSE AS THIS
10 CARGO PLANE IS GOING AND FLYING AROUND, OUR GAS IS
11 ONLY GOING DOWN; BUT EVERY ONCE IN A WHILE, WE LAND
12 AT AN AIRPORT AND SOMEBODY PUTS MORE AWARD ONTO OUR
13 PLANE. AND SO, YEAH, IT'S SOMETHING WE LOOK AT.
14 AND FORTUNATELY CHAIRMAN THOMAS, THIS IS SOMETHING
15 HE'S TAKEN UP TO DO, AND YOU WILL RECALL AT THE LAST
16 MEETING, I BELIEVE, HE IS GOING OUT AND ACTUALLY
17 SEEKING DONATIONS TO INCREASE THE ADMINISTRATIVE
18 BUCKET. IT'S SEVEN OR \$8 MILLION ALREADY AT THE
19 LAST MEETING HE ANNOUNCED. SO WE'RE VERY AWARE OF
20 IT. WE THINK ABOUT IT A LOT. WE DO WHAT WE CAN ON
21 OUR END, AND J.T. IS DOING OBVIOUSLY EVERYTHING HE
22 CAN TO ACTUALLY PUT SOME MORE GAS IN THE PLANE.

23 DR. DIXON: OKAY. THANKS.

24 DR. DULIEGE: RANDY, I JUST WANT TO
25 CONGRATULATE YOU AND THE TEAM AGAIN FOR SUCH A MAJOR

BARRISTERS' REPORTING SERVICE

1 OVERHAUL OF THE REVIEW PROCESS AND THE TRANSPARENCY
2 AND CLARITY OF THIS PROCESS THAT YOU HAD ON THIS
3 REALLY EXCELLENT SLIDE.

4 I ALSO WANTED TO MAKE COMMENT ON THE FACT
5 THAT ONE CLINICAL TRIAL CAME TO AN END. I JUST WANT
6 TO SAY IT'S NOT NECESSARILY DISAPPOINTMENT. YOU
7 KNOW THAT VERY WELL. IT'S SOMETHING THAT HAPPENS;
8 AND IF IT HAPPENS EARLY ON IN THE PROCESS OF A
9 CLINICAL TRIAL, IF RESEARCHERS DISCOVER THAT IT'S
10 GOING TO BE INEVITABLY A FUTILE EXERCISE, IT'S
11 POTENTIALLY GOOD TO HAVE THIS. JUST FOR THE RECORD,
12 IT'S PROBABLY A GOOD DECISION TO BE MADE.

13 DR. MILLS: THANK YOU VERY MUCH. AS YOU
14 KNOW, I GET TO STAND UP HERE AND TALK TO YOU ABOUT
15 THIS, BUT THE STRATEGIC PLAN AND THE CIRM 2.0
16 OVERHAUL AND EVERYTHING THAT GOES ON EVERY DAY IN
17 THIS ENGINE GOING ROUND AND ROUND IS BECAUSE OF THE
18 TEAM WE HAVE AT CIRM. AND I WAS HAVING A
19 CONVERSATION ABOUT THEM LAST NIGHT, AND THEY ARE
20 SOME OF THE FINEST PEOPLE I'VE EVER WORKED WITH.
21 DON'T TELL THEM THAT, BUT IT'S TRUE.

22 MR. JUELSGAARD: JUST TO FOLLOW UP ON
23 ANNE-MARIE'S QUESTION. SO THIS PHASE III TRIAL THAT
24 FAILED WAS ONE THAT -- THE FUNDING FOR THAT WAS
25 REVIEWED BY THE GWG; IS THAT CORRECT?

BARRISTERS' REPORTING SERVICE

1 DR. MILLS: THAT IS CORRECT.

2 MR. JUELSGAARD: WAS THE PHASE II DATA
3 THEN REVIEWED BY THE GWG?

4 DR. MILLS: THE PHASE II DATA WAS REVIEWED
5 BY THE GWG?

6 MR. JUELSGAARD: IN ORDER TO PROCEED TO
7 PHASE III.

8 DR. MILLS: CORRECT.

9 MR. JUELSGAARD: AND THEY FELT THAT THE
10 PHASE II DATA WAS COMPELLING ENOUGH TO, IN ESSENCE,
11 FUND THE PHASE III TRIAL; IS THAT CORRECT?

12 DR. MILLS: IT WAS MARGINAL. THE ULTIMATE
13 DECISION ENDED UP BEING A YES. THIS WAS THE FIRST
14 PROGRAM WE REVIEWED, AND THE VOTE WAS SPLIT ON IT
15 AND MARGINALLY GOT TO A TIER I.

16 MR. JUELSGAARD: WELL, FOR ME ONE OF THE
17 MOST IMPORTANT PARAMETERS OF DECIDING TO ADVANCE TO
18 PHASE III FROM PHASE II IS REALLY THAT PHASE II DATA
19 AND HOW SIGNIFICANT IT IS, NOT IN THE TERMS OF BEING
20 STATISTICALLY SIGNIFICANT, BUT THE DIFFERENCE
21 BETWEEN THE CONTROL GROUP AND THE TREATMENT GROUP.
22 SO --

23 DR. MILLS: SO HERE THIS IS WHERE -- AND
24 THIS HAPPENS A LOT IN PARTICULARLY CELL THERAPIES
25 AND STEM CELL THERAPIES. I'VE WATCHED THIS NOW BE

BARRISTERS' REPORTING SERVICE

1 THE DEMISE OF A LOT OF DIFFERENT THINGS. BUT WHEN I
2 TALK ABOUT WE HAVE ONE OF THE BIG SIX GOALS WHERE WE
3 HAVE TO PULL DOWN THAT TRANSLATIONAL TIME AND WE
4 HAVE TO GET THAT SHORTER OR I TALK ABOUT TIME, TIME,
5 TIME ALL THE TIME, THE PROBLEM THEY HAD WAS WHEN
6 THEY COLLECTED THEIR PHASE II DATA, IT WAS VERY
7 STRONG FOR THAT TIME AND THAT TREATMENT PARADIGM;
8 BUT THEY HAD SUCH SIGNIFICANT DELAYS GOING FROM
9 THERE INTO PHASE III, RAISING MONEY, GETTING THE
10 SPA, GETTING ALL THESE DIFFERENT THINGS, THAT TIME
11 WAS SO LONG, THAT THE WORLD CHANGED AND THE PARADIGM
12 CHANGED. SO WHAT WAS A BIG EFFECT SIZE SEVEN YEARS
13 AGO WHEN THEY RAN THEIR PHASE II TRIAL JUST NO
14 LONGER WAS THERE WHEN THEY FINALLY GOT AROUND TO RUN
15 THEIR PHASE III.

16 THAT'S WHY THIS CONTINUOUS RAILROAD TRACK,
17 SEAMLESS PROGRESSION FROM ONE TO ANOTHER AS FAST AS
18 WE POSSIBLY CAN GO, IS SO IMPORTANT. IF WE HAVE
19 THOSE KIND OF LONG DELAYS AND JUNCTIONS AND THINGS
20 LIKE THAT BETWEEN THESE DIFFERENT PROGRAMS, THAT
21 WILL BE A RECURRING THEME. SO TIME IS IMPORTANT.

22 MR. JUELGAARD: SO IF I UNDERSTOOD WHAT
23 YOU JUST SAID, IN ESSENCE, THIS WAS A PROGRAMMATIC
24 ISSUE. AND THAT IS THAT IN THE INTERIM OTHER
25 THERAPIES CAME TO THE FOREFRONT THAT MADE THE

BARRISTERS' REPORTING SERVICE

1 IMPORTANCE OF THIS THERAPY LESS IMPORTANT. IS THAT
2 A FAIR ASSESSMENT?

3 DR. MILLS: THAT WORLD IS CHANGING VERY
4 QUICKLY IN ONCOLOGY. AND DURING THE TIME WHEN THEY
5 GENERATED THEIR PHASE II DATA TO WHEN WE COULD START
6 THEIR PHASE III TRIAL, THEIR EFFECT SIZE WOULD NO
7 LONGER HAVE BEEN THERE BECAUSE OF OTHER IMPROVEMENTS
8 IN THERAPY.

9 MR. JUELSGAARD: HOW COULD WE DEAL WITH
10 THOSE PROGRAMMATIC ISSUES MORE EFFECTIVELY?

11 DR. MILLS: I THINK THIS IS WHY IT'S NICE
12 TO HAVE THINGS IN OUR PIPELINE AND NOT JUST LOBBED
13 IN AFTER A VERY LONG DELAY. IF THEY HAD DONE THE
14 PHASE II WITH US, WE WOULD HAVE SEAMLESSLY GONE FROM
15 PHASE II TO PHASE III. THEY WOULDN'T HAVE HAD THE
16 FUNDING DELAYS AND ISSUES AND HANG-UPS AND ALL OF
17 THOSE OTHER THINGS. I THINK THE ISSUE HERE IS
18 MAKING THE RELEVANT DATA YOU GOT TIED MORE CLOSELY
19 IN TIME TO WHEN YOU THEN TAKE THE NEXT APPROPRIATE
20 STEP. I JUST THINK THIS IS ALL ABOUT TIME.

21 DR. MELMED: IF I RECALL, THIS IS A
22 MELANOMA STUDY, CORRECT?

23 DR. MILLS: CORRECT.

24 DR. MELMED: THIS IS SOCIETAL GOOD NEWS
25 BECAUSE THERE HAS INDEED BEEN DRAMATIC REVOLUTIONARY

BARRISTERS' REPORTING SERVICE

1 CHANGES IN THE LAST 18 MONTHS. SO I THINK THAT THE
2 PROCESS APPEARS TO HAVE BEEN APPROPRIATE, AND THE
3 OUTCOME FOR SOCIETY WAS TERRIFIC, BUT FOR THIS
4 PROJECT WAS SUBOPTIMAL. SO I THINK YOUR PROCESS
5 QUESTION IS ACCURATE. I THINK THAT STAFF ACTED
6 APPROPRIATELY IN TERMS OF THE SOCIETAL IMPACT OF
7 MELANOMA PROGRESS.

8 DR. MILLS: I'LL ALSO SAY TOO THIS WAS A
9 CLEARLY IDENTIFIED RISK IN THE REVIEW. THIS DIDN'T
10 COME OUT OF LEFT FIELD AND SAY, WOW, WE JUST DIDN'T
11 SEE THIS AS A POSSIBILITY. THIS WAS WHY THE GWG WAS
12 RELATIVELY SPLIT ON THIS. IT ALSO, THOUGH, I THINK,
13 SAYS WE CAN TAKE THOSE RISKS NOW AND NOT HAVE THEM
14 COST \$20 MILLION. SO WE TOOK A SHOT AT THIS. WE
15 KNEW THAT THERE WAS A RISK. IT MIGHT HAVE WORKED.
16 IF IT WOULD HAVE WORKED -- THE END POINTS IN THIS
17 TRIAL WERE SURVIVAL. SO WE WERE FLAT OUT SWINGING
18 FOR SAVING PEOPLE'S LIVES. IT DIDN'T WORK AND IT
19 DIDN'T WORK IN A WAY WHICH STOPPED BASICALLY OUR
20 LOSS OR INVESTMENT ON THIS VERY, VERY QUICKLY IN.

21 IT WAS THREE MILLION OUT OF THE 20 MILLION
22 THAT GOT OUT, AND THEY SPENT MORE THAN THAT TOO. SO
23 WE WERE EQUAL PARTNERS IN ON THIS. AND SO I THINK
24 IT SHOWS THAT THE SYSTEM CAN ALLOW US TO TAKE SOME
25 CALCULATED RISKS, NOT RECKLESS RISKS, AND KNOW THAT

BARRISTERS' REPORTING SERVICE

1 WE CAN GET TO THESE ANSWERS, THESE GO/NO-GO ANSWERS,
2 STOP THE PROGRAM BEFORE WE HAVE JUST COMPLETELY
3 SPENT ALL THE MONEY.

4 DR. PRICE: JUST ASK A CLARIFICATION. YOU
5 REPEATED THIS PHRASE A COUPLE OF TIMES THAT IT
6 DIDN'T WORK. BUT FROM THE DISCUSSION, MY IMPRESSION
7 IS THAT IT MAY HAVE WORKED, BUT IT DIDN'T WORK AS
8 WELL AS SOME OTHER THERAPIES THAT ARE OUT THERE IN
9 THE MARKET.

10 DR. MILLS: IT DIDN'T WORK RELATIVE TO
11 STANDARD OF CARE TODAY WHERE IT DID WORK RELATIVE TO
12 STANDARD OF CARE YEARS AGO.

13 CHAIRMAN THOMAS: ANY OTHER QUESTIONS FOR
14 DR. MILLS? THANK YOU. I'LL TURN IT OVER NOW FOR
15 THE FINANCIAL REPORT TO MS. SILVA-MARTIN.

16 MS. SILVA-MARTIN: THANK YOU, MR. CHAIR.
17 GOOD MORNING, MEMBERS OF THE BOARD. THIS MORNING I
18 WILL BE REPORTING ON CIRM FINANCES. MY REPORT WILL
19 COVER OUR GRANT DISBURSEMENTS AND OUR CASH RESERVES,
20 OUR OPERATING EXPENSES FOR THE FIRST SIX MONTHS OF
21 THE FISCAL YEAR, AND THEN A SCHEDULE FOR THE
22 DEVELOPMENT OF THE '16-'17 BUDGET.

23 SO FIRST, A HIGH LEVEL OVERVIEW OF OUR
24 FINANCIAL STATUS. DURING THE FIRST EIGHT MONTHS OF
25 THIS FISCAL YEAR, WE DISBURSED A TOTAL OF \$119

BARRISTERS' REPORTING SERVICE

1 MILLION IN GRANT PAYMENTS, SLIGHTLY LOWER THAN WHAT
2 WE DISBURSED DURING THE SAME PERIOD IN THE '14-'15
3 FISCAL YEAR.

4 AS OF MARCH 1ST, WE HAD \$43 MILLION IN OUR
5 CASH RESERVES. IN ADDITION, WE'RE GETTING \$10
6 MILLION THIS MONTH FROM COMMERCIAL PAPER. ALSO, AMY
7 LEWIS FROM THE OFFICE OF THE CHAIR HAS BEEN WORKING
8 WITH THE STATE TREASURER'S OFFICE AND THE DEPARTMENT
9 OF FINANCE TO SECURE ADDITIONAL FUNDS FOR US EITHER
10 THROUGH THE SPRING OR FALL BOND SALES, AND THAT
11 REQUEST IS FOR \$117 MILLION. AND, OF COURSE, WE
12 CONTINUE TO HAVE ACCESS TO COMMERCIAL PAPER AS WE
13 NEED IT. SO ALL IN ALL, THIS IS PROVIDING US WITH A
14 VERY HEALTHY CASH RESERVE TO MEET OUR OPERATIONAL
15 EXPENSES.

16 SO NOW LOOKING AT OUR OPERATIONAL BUDGET,
17 THIS CHART REFLECTS OUR BUDGET AND EXPENSES FOR THE
18 FIRST SIX MONTHS OF THE FISCAL YEAR. SO AS YOU CAN
19 SEE, WE WERE ALLOCATED A TOTAL OF \$9.1 MILLION, AND
20 OUR SPEND RATE WAS JUST UNDER \$8.7 MILLION, LEAVING
21 A SAVINGS OF ABOUT \$400,000.

22 SO THERE ARE A FEW CATEGORIES WHERE WE
23 HAVE SIGNIFICANT VARIANCES, AND I WOULD JUST LIKE TO
24 TALK BRIEFLY ABOUT THOSE CATEGORIES AND WHY THE
25 VARIANCES -- THE SAVINGS HAVE OCCURRED OR THE LARGE

BARRISTERS' REPORTING SERVICE

1 VARIANCE IN THOSE AREAS.

2 SO FIRST OF ALL, WE HAVE A PRETTY
3 SIGNIFICANT VARIANCE IN OUR EMPLOYEE EXPENSES,
4 ALMOST \$800,000 IN SAVINGS. SO WHY DID THAT OCCUR?
5 WELL, THIS WAS DUE TO POSITIONS THAT WERE VACANT
6 DURING THE FIRST HALF OF THE YEAR. WE MADE A
7 DECISION TO HOLD THOSE POSITIONS VACANT UNTIL WE
8 COMPLETED THE STRATEGIC PLANNING PROCESS. WE ARE AT
9 THE VERY END OF THAT PROCESS. SO WE PLAN TO FILL
10 THE POSITIONS, AND WE DON'T ANTICIPATE SIMILAR
11 SAVINGS IN THE LAST HALF OF THE FISCAL YEAR.

12 WE ARE ALSO SEEING SOME SAVINGS IN OUR
13 REVIEW MEETINGS AND WORKSHOPS. THAT'S REALLY DUE TO
14 TWO FACTORS. SO WHEN WE DEVELOPED THE '15-'16
15 BUDGET FOR OUR CAP AND ALPHA CLINIC, WE HADN'T HELD
16 THOSE TYPES OF MEETINGS YET. SO WE MODELED IT AFTER
17 THE CDAP MEETINGS. WITH THE IMPLEMENTATION OF CIRM
18 2.0, HOWEVER, WE CHANGED HOW WE CONDUCT THOSE
19 MEETINGS. SO WE'RE NO LONGER MEETING AT A PRIVATE
20 VENUE, A HOTEL. WE ARE ACTUALLY HOLDING THOSE
21 MEETINGS AT THE GRANTEE LOCATION, AND SO IT'S
22 RESULTING IN SAVINGS FOR US.

23 AND I WANT TO POINT OUT THAT UNDER THE
24 CDAP MODEL, WE HELD ONE MEETING PER YEAR WITH EACH
25 OF OUR GRANTEES. AND UNDER OUR NEW MODEL, WE'RE

BARRISTERS' REPORTING SERVICE

1 HOLDING FOUR MEETINGS A YEAR, AND STILL WE'RE HAVING
2 COST SAVINGS.

3 AND THEN THE OTHER FACTOR THAT'S
4 REFLECTING A SAVINGS HERE IS OUR ICOC BOARD
5 MEETINGS. WE ARE HAVING SAVINGS IN THAT AREA TOO
6 BECAUSE WE'RE NOT HOLDING AS MANY IN-PERSON
7 MEETINGS.

8 SO THE LAST CATEGORY I WANT TO TALK ABOUT
9 IS OUR FACILITIES RELOCATION. THAT'S A NEW
10 CATEGORY. FOR THE FIRST TIME IN CIRM'S HISTORY, WE
11 ARE NOW HAVING TO PAY RENT. IN THIS FISCAL YEAR, WE
12 INCURRED SOME ONETIME COSTS AS A RESULT OF US MOVING
13 TO OUR NEW OFFICES. SO THE VARIANCE IN THIS
14 CATEGORY IS REALLY DUE TO OUR SPACE. SO WHEN WE
15 ACQUIRED OUR SPACE, IT WAS A SHELL. SO WE HAD TO
16 BUILD IT OUT. SO WE HAD BASICALLY TWO OPTIONS FOR
17 MAKING THE PAYMENT FOR THAT BUILDOUT. WE COULD HAVE
18 EITHER ROLLED IT INTO THE MONTHLY LEASE PAYMENTS,
19 BUT THAT WOULD HAVE RESULTED IN INCREASED COST
20 BECAUSE WHAT WOULD HAVE HAPPENED IS THE OWNERSHIP
21 WOULD HAVE HAD TO PAY FOR THESE COSTS UP FRONT. IN
22 ORDER FOR THEM TO DO THAT, THEY WOULD HAVE HAD TO
23 SECURE FUNDING, AND THE COST OF THAT FINANCING WOULD
24 HAVE BEEN PASSED ON TO US IN THE FORM OF HIGHER
25 LEASE PAYMENTS THROUGH THE TERM OF THE FIVE-YEAR

BARRISTERS' REPORTING SERVICE

1 LEASE.

2 OUR OTHER OPTION WAS TO PAY THE COST UP
3 FRONT WHICH WOULD RESULT IN SIGNIFICANT SAVINGS TO
4 THE STATE. SO THAT'S THE OPTION THAT WE SELECTED
5 BECAUSE IT WAS BEST, MOST BENEFICIAL FOR THE STATE
6 OF CALIFORNIA.

7 AND THEN LAST I JUST WANTED TO BRIEF YOU
8 ON OUR PROGRESS SO FAR IN THE DEVELOPMENT OF THE
9 '16-'17 BUDGET. SO DURING THE LAST FEW MONTHS, THE
10 COST CENTERS HAVE BEEN WORKING WITH US TO DEVELOP
11 THEIR BUDGET REQUESTS. WE ARE TWEAKING THOSE BUDGET
12 REQUESTS, AND WE PLAN TO PRESENT TO THE PRESIDENT
13 AND THE CHAIR PROBABLY SOMETIME IN APRIL. WE WILL
14 THEN SHARE THOSE FINAL NUMBERS WITH OUR FINANCE
15 SUBCOMMITTEE CHAIRMAN, AND THEN WE PLAN TO BRING IT
16 TO A FINANCE SUBCOMMITTEE IN LATE MAY AND TO THIS
17 BOARD IN JUNE FOR A FINAL REVIEW AND APPROVAL.

18 THAT CONCLUDES MY PRESENTATION. ARE THERE
19 ANY QUESTIONS?

20 MR. JUELSGAARD: SO IN THE PAST COUPLE
21 YEARS, CHILA, ONE OF THE THINGS THAT AT LEAST I'VE
22 ASKED FOR AND I'M HOPEFUL THAT WE HAVE IT THIS YEAR
23 IS THE ABILITY TO LOOK AT BUDGET VERSUS CURRENT YEAR
24 RUN RATE TO LOOK AT WHAT WE'RE ASKING FOR VERSUS
25 WHAT WE'VE BEEN SPENDING AS OPPOSED TO JUST PREVIOUS

BARRISTERS' REPORTING SERVICE

1 YEAR'S BUDGETS.

2 MS. SILVA-MARTIN: YES, I WILL PROVIDE YOU
3 THAT. ABSOLUTELY. ANYBODY ELSE? THANK YOU VERY
4 MUCH.

5 CHAIRMAN THOMAS: THANK YOU, CHILA. I
6 WOULD, FURTHER TO THE POINT SHE WAS MAKING ABOUT
7 FACILITIES AND RELOCATION, NOTE THAT WE HAVE BEEN IN
8 THERE SINCE AROUND THE FIRST OF DECEMBER AND WOULD
9 WELCOME ANY OF YOU WHO ARE FINDING YOURSELVES IN THE
10 OAKLAND AREA TO COME BY TO VISIT BECAUSE THE SPACE
11 IS A REALLY BEAUTIFULLY BUILT OUT SPACE IN A VERY
12 NICE PART OVERLOOKING LAKE MERRITT. AND I THINK
13 EVERYBODY IS NOW FIRMLY ENSCONCED THERE, AND WE'VE
14 HAD A NUMBER OF FOLKS TO COME BY FOR MEETINGS WHO
15 HAVE REMARKED HOW NICE IT LOOKS. AND, AGAIN, AS YOU
16 RECALL FROM THE DECEMBER MEETING, THAT WHOLE PROJECT
17 WAS OVERSEEN BY MANDA, WHO RANDY CONGRATULATED, AND
18 DID AN OUTSTANDING JOB. SO I WOULD WELCOME
19 EVERYBODY TO COME BY. I THINK YOU'LL BE VERY HAPPY
20 WITH IT. AND SO JUST WANTED TO MAKE THAT POINT.

21 CHILA, THANK YOU VERY MUCH. AGAIN, ALL
22 THESE FISCAL MATTERS SEEM TO BE SORT OF CLICKING
23 ALONG AS A MATTER OF ROUTINE, BUT THERE IS A TON OF
24 WORK THAT GOES INTO THIS BY CHILA AND HER TEAM AND
25 WITH THE STATE WITH AMY LEWIS AND INTERFACING WITH

BARRISTERS' REPORTING SERVICE

1 THE DEPARTMENT OF FINANCE AND THE TREASURER'S
2 OFFICE. WE KIND OF TAKE ALL THE FISCAL ISSUES FOR
3 GRANTED, BUT JUST WANT EVERYBODY TO KNOW THAT IT'S
4 THE PRODUCT OF A GREAT DEAL OF WORK.

5 WE NOW HAVE NEXT ON THE AGENDA THE
6 PROPOSED CONSENT CALENDAR. THERE ARE A COUPLE OF
7 ITEMS ON THERE: CONSIDERATION OF APPOINTMENT OF NEW
8 SCIENTIFIC MEMBERS TO THE GWG AND CONSIDERATION OF
9 MINUTES FROM THE JANUARY AND FEBRUARY 2016 ICO BOARD
10 MEETINGS. ANYBODY WANT TO TAKE EITHER OF THOSE OFF
11 FOR A SEPARATE VOTE? HEARING NONE, I THINK WE CAN
12 DO A VOICE VOTE ON THIS ONE, JAMES; IS THAT CORRECT?

13 MR. SHEEHY: I JUST WANTED TO MAKE A QUICK
14 COMMENT. ONE OF THE MEMBERS BEING REAPPOINTED TO
15 THE GRANTS WORKING GROUP IS JOSE CIBELLI. SOME OF
16 US HAVE BEEN ON THE WORKING GROUP FOR A WHILE. I
17 JUST WANT TO NOTE HIS CONTRIBUTIONS. HE'S BEEN ON
18 BOTH THE STANDARDS WORKING GROUP AND THE GRANTS
19 WORKING GROUP, I THINK, FROM THE BEGINNING. I KNOW
20 ON THE STANDARDS WORKING GROUP FROM THE BEGINNING.
21 AND HIS CONTRIBUTIONS HAVE BEEN ENORMOUS.

22 AND ONE OF THE THINGS WE DON'T ALWAYS
23 RECOGNIZE IS HOW HARD THE REVIEWERS WORK. AND FOR
24 MANY OF THEM IT'S A SACRIFICE AND THEY DO THIS
25 BECAUSE THEY'RE COMMITTED TO THE WORK WE'RE DOING.

BARRISTERS' REPORTING SERVICE

1 DR. CIBELLI FALLS IN THAT CATEGORY. SO I JUST
2 WANTED TO NOTE HIS SERVICE TO THE STATE OF
3 CALIFORNIA AS WE'RE REUPPING HIM.

4 CHAIRMAN THOMAS: THANK YOU, MR. SHEEHY.
5 I WOULD LIKE TO REITERATE A POINT JEFF SAID. FOR
6 THOSE OF YOU WHO'VE NOT ACTUALLY BEEN IN ONE OF THE
7 GRANTS WORKING GROUP MEETINGS, THEY ARE QUITE
8 EXTRAORDINARY IN THE LEVEL OF EFFORT AND DILIGENCE
9 AND REAL SENSE OF DUTY BROUGHT TO BEAR BY ALL
10 MEMBERS OF THE COMMITTEE AND MAKE FOR VERY SPIRITED
11 DISCUSSIONS THAT YIELD, I THINK, A VERY GOOD RESULT.
12 AND EVERYBODY SHOULD KNOW THAT THAT PROCESS, WHICH
13 IS CRUCIAL TO THE SUCCESS OF CIRM, IS ONE THAT IS
14 TRULY IMPRESSIVE, AND WE DO VERY MUCH APPRECIATE
15 EVERYBODY'S PARTICIPATION, AS MR. SHEEHY SAID.

16 MR. HARRISON, CAN WE DO A VOICE VOTE ON
17 THIS? DO WE HAVE A MOTION TO APPROVE THE CONSENT
18 CALENDAR?

19 MS. WINOKUR: SO MOVED.

20 DR. DULIEGE: SECOND.

21 CHAIRMAN THOMAS: MOVED BY MS. WINOKUR,
22 SECONDED BY DR. DULIEGE. ALL THOSE IN FAVOR PLEASE
23 SAY AYE. OPPOSED? LET'S SEE. MARIA, CAN YOU POLL
24 THOSE ON THE PHONE?

25 MS. BONNEVILLE: JACK DIXON. AL ROWLETT.

BARRISTERS' REPORTING SERVICE

1 MR. ROWLETT: AYE.

2 MS. BONNEVILLE: CARL WARE.

3 DR. WARE: YES.

4 CHAIRMAN THOMAS: MOTION IS APPROVED.

5 MOVE ON TO ACTION ITEMS NOW. MR. SENATOR.

6 MR. TORRES: I'LL BE VERY BRIEF. I WANTED
7 TO PROPOSE THAT WE ADJOURN IN THE MEMORY OF NANCY
8 REAGAN TODAY. NO ONE PROVIDED MORE SUPPORT FOR THIS
9 INITIATIVE AT A VERY CRUCIAL TIME IN 2004 THAN HER
10 COURAGEOUS POSITION TO SUPPORT STEM CELL RESEARCH.
11 I KNEW HER, I KNEW THE PRESIDENT; BUT MORE
12 IMPORTANTLY, HER WORK AND HER COMMITMENT TO THIS
13 EFFORT WILL HOPEFULLY SAVE MANY LIVES AS WE ALL WORK
14 TOGETHER. AND I WOULD REQUEST THAT WE ADJOURN IN
15 HER MEMORY TODAY.

16 CHAIRMAN THOMAS: THANK YOU VERY MUCH,
17 MR. SENATOR. WELL SAID.

18 ACTION ITEMS, FIRST NO. 9, CONSIDERATION
19 OF APPLICATIONS SUBMITTED IN RESPONSE TO CLIN1,
20 WHICH IS PARTNERING OPPORTUNITY FOR LATE STAGE
21 PRECLINICAL PROJECTS, AND CLIN2, PARTNERING
22 OPPORTUNITY FOR CLINICAL TRIAL STAGE PROJECTS.
23 WE'LL HEAR FIRST FROM DR. JORGENSON.

24 DR. JORGENSON: GOOD MORNING. I'M GOING
25 TO PRESENT FOR YOUR CONSIDERATION THE OUTCOMES OF

BARRISTERS' REPORTING SERVICE

1 THIS SPIRITED DISCUSSION OF OUR GRANTS WORKING GROUP
2 FROM THE FEBRUARY 23D REVIEW OF APPLICATIONS
3 RECEIVED IN RESPONSE TO THE CIRM CLINICAL PROGRAM.

4 AS A REMINDER, AS YOU ALL KNOW, WE HAVE
5 THREE PROGRAM ANNOUNCEMENTS THAT ARE AVAILABLE UNDER
6 THE CIRM CLINICAL PROGRAM: CLIN1, WHICH IS FOR LATE
7 STAGE PRECLINICAL PROJECTS; CLIN2, WHICH IS FOR
8 CLINICAL TRIAL STAGE PROJECTS; AND CLIN3, WHICH IS
9 OPEN TO CIRM GRANTEEES WHO HAVE AWARDS UNDER THE
10 CLINICAL PROGRAM WHO WANT TO PROPOSE SUPPLEMENTAL
11 ACCELERATING ACTIVITIES.

12 THE SCORING SYSTEM, AS RANDY PRESENTED IN
13 HIS PRESENTATION EARLIER, IS THAT A SCORE OF 1 MEANS
14 THAT THE GRANTS WORKING GROUP THOUGHT THE
15 APPLICATION HAS EXCEPTIONAL MERIT AND WARRANTS
16 FUNDING. A SCORE OF 2 MEAN THAT THE GRANTS WORKING
17 GROUP VOTED THAT THE APPLICATION NEEDS IMPROVEMENT
18 AND DOES NOT WARRANT FUNDING AT THIS TIME, BUT COULD
19 BE RESUBMITTED TO ADDRESS AREAS OF IMPROVEMENT. A
20 SCORE OF 3 INDICATES THAT THE GRANTS WORKING GROUP
21 HAS FOUND THE APPLICATION TO BE SUFFICIENTLY FLAWED
22 THAT IT DOES NOT WARRANT FUNDING AND THAT THE SAME
23 PROJECT SHOULD NOT BE RESUBMITTED.

24 THE APPLICATIONS ARE SCORED BY ALL
25 SCIENTIFIC MEMBERS OF THE GWG WHO ARE NOT IN

BARRISTERS' REPORTING SERVICE

1 CONFLICT WITH THE APPLICATION THAT'S BEING
2 CONSIDERED.

3 THE FIRST APPLICATION I WANT TO PRESENT IS
4 A CLIN2 APPLICATION, CLIN2-8334. THIS IS A PROPOSAL
5 TO USE ALLOGENEIC-DERIVED CARDIOSPHERE-DERIVED
6 CELLS, CAP-1002, TO TREAT PATIENTS WITH DUCHENNE'S
7 MUSCULAR DYSTROPHY CARDIOMYOPATHIES. THE APPLICANT
8 PROPOSED TO COMPLETE A RANDOMIZED OPEN LABEL PHASE
9 II CLINICAL TRIAL TO TEST THE SAFETY AND EFFICACY OF
10 CAP-1002 IN THE PATIENT POPULATION.

11 THE MAJOR PROPOSED ACTIVITIES WERE TO
12 MANUFACTURE CAP-1002 IN SUFFICIENT QUANTITIES TO
13 TREAT ALL SUBJECTS ENROLLED IN THE TRIAL AND TO
14 ENROLL AND TREAT ALL SUBJECTS ACCORDING TO THE
15 PROPOSED CLINICAL PROTOCOL. AND THE APPLICANT
16 REQUESTED APPROXIMATELY \$3.4 MILLION AND PROVIDED
17 \$2.3 MILLION IN CO-FUNDING.

18 PRIOR TO FORWARDING APPLICATIONS TO
19 REVIEW, THE APPLICATIONS UNDERGO A BUDGET REVIEW,
20 WHICH THIS APPLICATION PASSED, WHICH INDICATES THAT
21 THE BUDGET IS APPROPRIATE FOR THE PROPOSED
22 ACTIVITIES.

23 THIS PARTICULAR APPLICATION WAS REVIEWED
24 ON THREE OCCASIONS BY THE GRANTS WORKING GROUP. THE
25 LAST REVIEW, WHICH WAS THE FEBRUARY 23D REVIEW, IT

BARRISTERS' REPORTING SERVICE

1 RECEIVED A SCORE OF 1, INDICATING THE WORKING GROUP
2 FIND IT TO HAVE EXCEPTIONAL MERIT AND WARRANT
3 FUNDING. TWELVE MEMBERS OF THE GWG VOTED FOR A
4 SCORE OF 1 WITH ONE MEMBER VOTING FOR A SCORE OF 2.
5 THE CIRM TEAM RECOMMENDATION IS TO FUND THE
6 APPLICATION IN THE AMOUNT REQUESTED BY THE APPLICANT
7 OF \$3.4 MILLION, AND THIS CONCURS WITH THE GWG
8 RECOMMENDATION.

9 I ALSO WANT TO REPORT ON THE NEW VOTING
10 PROCESS THAT THIS BOARD APPROVED IN DECEMBER OF LAST
11 YEAR. YOU MAY RECALL THAT WE WANTED TO PUT A VOTE
12 FOLLOWING THE REVIEW OF AN INDIVIDUAL APPLICATION
13 THAT INDICATES THAT THE REVIEW PANEL FEELS THAT THE
14 REVIEW PROCESS HELD INTEGRITY. SO THE FIRST VOTE IS
15 TAKEN BY ALL MEMBERS OF THE GWG. THAT MEANS THE
16 SCIENTIFIC AND THE PATIENT ADVOCATE MEMBERS. AND
17 THEY VOTE WHETHER OR NOT THEY FELT THE REVIEW WAS
18 SUFFICIENTLY SCIENTIFICALLY RIGOROUS, WHETHER THERE
19 WAS SUFFICIENT TIME FOR ALL VIEWPOINTS TO BE HEARD,
20 AND WHETHER THE SCORES REFLECT THE RECOMMENDATIONS
21 OF THE GWG.

22 WE THEN TAKE A SECOND VOTE TAKEN IS THE
23 PATIENT ADVOCATE MEMBERS. THE ICOC PATIENT ADVOCATE
24 MEMBERS ARE THE ONLY MEMBERS WHO VOTE ON THIS VOTE.
25 AND THEY VOTE WHETHER OR NOT THE REVIEW WAS CARRIED

BARRISTERS' REPORTING SERVICE

1 OUT IN A FAIR MANNER AND FREE FROM UNDUE BIAS. FOR
2 THIS PARTICULAR APPLICATION, ALL MEMBERS VOTED
3 UNANIMOUSLY IN FAVOR OF VOTE ONE, AND ALL ICOC
4 MEMBERS VOTED UNANIMOUSLY IN FAVOR OF VOTE TWO.

5 SO AT THIS TIME I CAN TAKE ANY QUESTIONS
6 ABOUT THE REVIEW PROCESS, OR HAND THE MIC OVER TO
7 MR. SHEEHY TO DISCUSS.

8 MR. SHEEHY: SO NOW WE'RE IN THE
9 APPLICATION REVIEW SUBCOMMITTEE, JUST TO BE CLEAR
10 THAT WE'RE TRANSITIONING.

11 SO IS THERE A MOTION TO ACCEPT THE GRANTS
12 WORKING GROUP RECOMMENDATION?

13 MR. TORRES: SO MOVED.

14 DR. PRICE: SECOND.

15 MR. SHEEHY: DO WE HAVE A SECOND?

16 MR. ROWLETT: I WILL SECOND.

17 MR. HARRISON: WE JUST WANTED
18 CLARIFICATION ABOUT WHICH APPLICATION YOU'RE
19 REFERRING TO BECAUSE ONE OF THEM -- FOR ONE OF
20 THEM --

21 MR. SHEEHY: WE'RE JUST WORKING ON THE ONE
22 APPLICATION THAT'S BEEN PRESENTED. CAN THE SECOND
23 COME FROM ANY MEMBER?

24 MR. HARRISON: THE SECOND CAN COME ONLY
25 FROM A MEMBER OF THE APPLICATION REVIEW

BARRISTERS' REPORTING SERVICE

1 SUBCOMMITTEE.

2 MR. SHEEHY: SORRY, DR. PRICE. I
3 APOLOGIZE.

4 DR. DULIEGE: SECOND.

5 MR. SHEEHY: DR. DULIEGE IS THE SECOND.
6 SO IS THERE ANY DISCUSSION AMONGST BOARD MEMBERS?

7 MR. HARRISON: THE MOTION NEEDS TO BE MADE
8 BY A MEMBER OTHER THAN SENATOR TORRES, ANOTHER
9 MEMBER OF THE APPLICATION REVIEW SUBCOMMITTEE. I
10 APOLOGIZE FOR THE CONFUSION, BUT THIS IS 8334 THAT
11 IS THE SUBJECT OF THE DISCUSSION. SO ANOTHER MEMBER
12 OF THE APPLICATION REVIEW SUBCOMMITTEE.

13 DR. HIGGINS: SO MOVED.

14 MR. SHEEHY: IT'S MOVED BY DR. HIGGINS AND
15 SECONDED BY DR. DULIEGE. AND THEN IS THERE A
16 DISCUSSION ON THIS?

17 DR. DULIEGE: MORE CLARIFICATION BECAUSE
18 WITH THAT RECOMMENDATION WE'RE PROBABLY GOING TO BE
19 IN FAVOR. WHAT IS IT? IS IT A PHASE II TRIAL,
20 FIRST TIME IN HUMANS? WHAT'S THE STAGE OF THE
21 CLINICAL TRIAL? WHAT'S THE STAGE OF THIS EFFORT?
22 IS IT --

23 DR. JORGENSON: IT'S A PHASE II CLINICAL
24 TRIAL, YES. IT'S THE FIRST TIME THIS PRODUCT WILL
25 BE GOING TOWARDS THIS INDICATION, BUT THIS

BARRISTERS' REPORTING SERVICE

1 PARTICULAR PRODUCT HAS BEEN IN OTHER CLINICAL
2 TRIALS.

3 DR. DULIEGE: OKAY. IT'S INTERESTING.
4 JUST BRIEFLY, CAN YOU EXPAND ON IT A LITTLE BIT JUST
5 SO THAT WE HAVE A SENSE, BASED ON OUR LAST
6 DISCUSSION, ABOUT POTENTIALLY THE CHANCE OF SUCCESS
7 OR RISK THERE?

8 DR. JORGENSON: ABOUT THE REVIEW CONCERNS?

9 DR. DULIEGE: HOW THE PREVIOUS RESULTS MAY
10 JUSTIFY THIS TRIAL.

11 DR. JORGENSON: SO I'M TRYING TO FIGURE
12 OUT WHAT I CAN SAY IN A NONCONFIDENTIAL SESSION. SO
13 THIS TRIAL IS IN DUCHENNE'S MUSCULAR DYSTROPHY
14 PATIENTS WHO HAVE CARDIOMYOPATHIES. THIS PRODUCT
15 HAS BEEN IN A NUMBER OF OTHER TRIALS IN OTHER
16 INDICATIONS, NOT A CARDIOMYOPATHY AND NOT DUCHENNE'S
17 MUSCULAR DYSTROPHY. THERE WAS A LOT OF DISCUSSION
18 IN THE REVIEW, AND YOU CAN READ COMMENTS
19 SPECIFICALLY IN THE SUMMARY IF YOU LOOK, BUT THERE
20 WAS A LOT OF DISCUSSION IN THE REVIEW ABOUT THAT
21 BODY OF DATA AND ABOUT THE PRECLINICAL DATA AND
22 WHETHER OR NOT THAT SUPPORTED A LIKELIHOOD OF
23 EFFICACY. THERE WEREN'T REALLY SERIOUS CONCERNS
24 REGARDING SAFETY. THAT SEEMS TO BE CLEAR. IT'S
25 PRIMARILY AN ISSUE OF EFFICACY, AND THAT WAS LARGELY

BARRISTERS' REPORTING SERVICE

1 WHAT THE RE-REVIEWS WERE ABOUT.

2 IN THE FIRST TWO REVIEWS, THERE WERE
3 CONCERNS EXPRESSED. THE CONCERNS WENT BACK TO THE
4 APPLICANT. THE APPLICANT PROVIDED RESPONSES. AND
5 IN THE THIRD REVIEW, THE COMMENTS FROM THE REVIEWERS
6 WERE THAT THEY'VE PROVIDED ENOUGH EXPLANATION AND
7 ENOUGH DETAIL FROM THE CLINICAL DATA, WHICH I THINK
8 IS NOT RELEASED CLINICAL DATA. THEY PROVIDED DATA
9 THAT THEY HAD WHICH HAS NOT BEEN PUBLICLY RELEASED.
10 AND THE REVIEW PANEL FELT CONFIDENT ENOUGH. AS YOU
11 SAW THE PREVIOUS SLIDE, THE VOTE WAS 12 TO 1.

12 BUT IT WAS A TOPIC OF HEALTHY DEBATE. I
13 DON'T THINK I CAN PROVIDE A LOT MORE DETAIL THAN
14 THAT IN A PUBLIC SESSION.

15 DR. DULIEGE: THAT'S COMPLETELY
16 UNDERSTANDABLE, BUT THIS ACTUALLY IS A RE-REVIEW.
17 IT'S THE SECOND TIME --

18 DR. JORGENSON: IT WAS REVIEWED THREE
19 TIMES ACTUALLY. SO IT CAME IN INITIALLY AND WAS
20 REVIEWED INITIALLY IN DECEMBER. COMMENTS WERE SENT
21 TO THE APPLICANT. IT WAS REVIEWED AGAIN IN JANUARY,
22 AND THEN IT WAS REVIEWED AGAIN IN FEBRUARY. AND SO
23 THE PRIMARY ISSUE IN THE FIRST TWO REVISIONS WAS
24 EXACTLY THE CONCERN YOU RAISED.

25 AND ON THE SECOND REVISION OR THE THIRD

BARRISTERS' REPORTING SERVICE

1 TIME IT WAS REVIEWED, THE REVIEW PANEL FELT THAT THE
2 CONCERN HAD BEEN ADEQUATELY ADDRESSED IN SUFFICIENT
3 DETAIL FOR THEM TO FEEL COMFORTABLE VOTING TO
4 RECOMMEND TO FUND IT.

5 DR. DULIEGE: GREAT. THANKS FOR THAT
6 CLARIFICATION. AND, AGAIN, BASED ON WHAT YOU JUST
7 SAID, I WANT TO APPLAUD THE PROCESS WHERE WE END UP
8 HAVING -- I DON'T KNOW IF WE HAVE MUCH TO VOTE WHEN
9 YOU HAVE SUCH UNANIMOUS COMMENT, BUT IT MEANS THAT
10 REALLY IT HAS BEEN TOTALLY SUPPORTED BY THE GRANTS
11 WORKING GROUP, WHICH IS GREAT.

12 AND THE SECOND GREAT THING IS IT COMES
13 FROM WITHIN A MONTH. SO IT'S NOT THAT THE
14 APPLICANTS HAD TO SPEND SO MUCH TIME IN REVIEWS, AND
15 THIS HAS BEEN REALLY A PROMPT PROCESS, WHICH IS
16 GREAT.

17 MR. SHEEHY: ARE THERE OTHER BOARD
18 MEMBERS? DR. JUELSGAARD AND THEN DR. STEWARD.

19 MR. JUELSGAARD: YES, JUST A QUICK
20 QUESTION. WAS THERE A REVIEW WITH THE FDA OF THE
21 THIS PROPOSED PHASE II CLINICAL TRIAL, DO YOU KNOW?

22 DR. JORGENSON: YEAH. THE TRIAL IS OPEN.
23 THE TRIAL IS ACTUALLY ONGOING.

24 DR. STEWARD: I JUST WANTED TO ACTUALLY GO
25 BACK AND SORT OF REINFORCE WHAT RANDY WAS TALKING

BARRISTERS' REPORTING SERVICE

1 ABOUT EARLIER ON BECAUSE I THINK THIS IS AN
2 EXCELLENT EXAMPLE OF THIS NEW PROCESS THAT YOU PUT
3 IN PLACE THAT I THINK IS WORKING REALLY, REALLY WELL
4 WHERE WE'RE NOT GOING TO BE REACHING DOWN AND
5 LOOKING AT THINGS THAT AREN'T QUITE RIGHT WHEN THEY
6 COULD BE A LITTLE BIT BETTER. AS YOU SAID, THE IDEA
7 WOULD BE TO HAVE ALL OF THESE THINGS NOW COME
8 FORWARD AS SORT OF SCORING 95. SO IT TOOK WHATEVER,
9 THREE ROUNDS ON THIS ONE, AND EACH TIME IT WAS
10 IMPROVED. I JUST THINK IT REALLY IS A GREAT MARK OF
11 A GOOD PROCESS THAT YOU PUT IN PLACE. SO THANKS,
12 RANDY.

13 MR. SHEEHY: OTHER BOARD QUESTIONS OR
14 COMMENTS? ANY PUBLIC COMMENT?

15 DR. MARBAN: GOOD MORNING. MY NAME IS
16 LINDA MARBAN. I'M THE CEO OF CAPRICOR. AND THANK
17 YOU FOR ALLOWING ME TO ATTEND THIS MEETING.

18 I'D LIKE TO DIRECTLY ADDRESS YOUR
19 QUESTIONS AND PROVIDE SOME INFORMATION TO YOU THAT I
20 THINK WILL BE RELEVANT TO YOU AND ALSO MAKES US VERY
21 PROUD. FIRST OF ALL, THIS TRIAL IS ENROLLING. YOU
22 WILL HEAR TOMORROW THAT WE ACTUALLY WILL HAVE
23 COMPLETED THE ENROLLMENT OF THE FIRST COHORT IN FIVE
24 WEEKS TIME. WE'RE PAUSING FOR A SAFETY REVIEW,
25 WHICH IS TERRIFIC.

BARRISTERS' REPORTING SERVICE

1 WE HAVE BEEN TREATING BOYS THAT ARE
2 AMBULATORY AND NONAMBULATORY. WE'RE PROVIDING ONE
3 OF THE ONLY OPPORTUNITIES IN CLINICAL TRIALS FOR
4 BOYS AND YOUNG MEN WITH DUCHENNE'S MUSCULAR
5 DYSTROPHY THAT IS AGNOSTIC TO THE TYPE OF MUTATION
6 OR THE TYPE OF DYSTROPHIN DISORDER THAT THEY HAVE.
7 SO WE'VE HAD PARENTS ACTUALLY CRYING IN THE HALLWAY
8 OF THE HOSPITALS THANKING US FOR THE OPPORTUNITY TO
9 HAVE THEIR CHILD IN A CLINICAL TRIAL.

10 IN ANSWER TO WHETHER THIS HAS BEEN DONE
11 CLINICALLY BEFORE, WE HAVE THREE CLINICAL TRIALS
12 WHICH WE'VE CONDUCTED, CADUCEUS, ALL STAR PHASE I,
13 AND THE DYNAMIC TRIAL WHERE WE'VE SHOWN REDUCTION IN
14 THE AMOUNT OF SCAR THAT HAS DAMAGED THE HEART AND
15 IMPROVEMENT IN CARDIAC FUNCTION IN PATIENTS THAT
16 HAVE BEEN TREATED WITH OUR CELLS.

17 IN DUCHENNE'S MUSCULAR DYSTROPHY, THE
18 CARDIOMYOPATHY IS DEFINED BY THE AGGREGATION OF
19 SCAR. THAT MEANS AS THE DYSTROPHIN MUTATION OCCURS,
20 MUSCLE CELLS DIE, YOU GET SCAR AND FIBROSIS
21 OCCURRING. WE BELIEVE THAT OUR CELLS WILL GO IN
22 THERE AND ACTUALLY REDUCE THE AMOUNT OF SCAR, DRIVE
23 THE BOYS BACK POTENTIALLY FROM DECOMPENSATED TO
24 COMPENSATED HEART FAILURE, AND PROVIDE AN
25 OPPORTUNITY FOR THEM TO CONTINUE LONGER AND WITH A

BARRISTERS' REPORTING SERVICE

1 BETTER QUALITY OF LIFE WHILE WE LOOK FOR A CURE FOR
2 THIS DEVASTATING DISEASE.

3 THANK YOU FOR YOUR SUPPORT. I CONCUR THAT
4 THE NEW 2.0 IS WORKING VERY WELL. WE'VE GOTTEN A
5 LOT OF REALLY GOOD FEEDBACK AND ENJOY CONTINUING OUR
6 YEARS OF RELATIONSHIP WITH THE CALIFORNIA INSTITUTE
7 FOR REGENERATIVE MEDICINE. THANK YOU.

8 MR. SHEEHY: THANK YOU, DR. MARBAN. ANY
9 OTHER PUBLIC COMMENT? THEN, MS. BONNEVILLE, COULD
10 YOU CALL THE ROLL, PLEASE.

11 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

12 DR. DULIEGE: YES.

13 MS. BONNEVILLE: DAVID HIGGINS.

14 DR. HIGGINS: YES.

15 MS. BONNEVILLE: STEVE JUELSGAARD.

16 MR. JUELSGAARD: YES.

17 MS. BONNEVILLE: SHERRY LANSING. KATHY
18 LAPORTE.

19 MS. LAPORTE: YES.

20 MS. BONNEVILLE: LAUREN MILLER.

21 MS. MILLER: YES.

22 MS. BONNEVILLE: ADRIANA PADILLA.

23 DR. PADILLA: YES.

24 MS. BONNEVILLE: JOE PANETTA.

25 MR. PANETTA: YES.

BARRISTERS' REPORTING SERVICE

1 MS. BONNEVILLE: FRANCISCO PRIETO. ROBERT
2 QUINT.

3 DR. QUINT: YES.

4 MS. BONNEVILLE: AL ROWLETT.

5 MR. ROWLETT: YES.

6 MS. BONNEVILLE: JEFF SHEEHY.

7 MR. SHEEHY: YES.

8 MS. BONNEVILLE: OS STEWARD.

9 DR. STEWARD: YES.

10 MS. BONNEVILLE: JONATHAN THOMAS.

11 CHAIRMAN THOMAS: YES.

12 MS. BONNEVILLE: DIANE WINOKUR.

13 MS. WINOKUR: YES.

14 DR. DIXON: THIS IS JACK DIXON. I VOTE
15 YES AS WELL. I WAS IN THE RESTROOM.

16 MR. HARRISON: THANK YOU, DR. DIXON. THIS
17 IS A MOTION OF THE APPLICATION REVIEW SUBCOMMITTEE,
18 AND YOU ARE AN EX OFFICIO, NONVOTING MEMBER OF THAT
19 SUBCOMMITTEE.

20 DR. DIXON: ALL RIGHT. THANK YOU.

21 MR. SHEEHY: THANK YOU. SO NOW I'LL PASS
22 THE CHAIR OVER TO DR. STEWARD BECAUSE I BELIEVE I
23 HAVE A CONFLICT ON THE NEXT APPLICATION THAT'S GOING
24 TO BE DISCUSSED. I JUST WANTED TO SAY ONE THING
25 ABOUT THE APPLICATION WE JUST REVIEWED.

BARRISTERS' REPORTING SERVICE

1 THIS IS PRETTY MUCH A PURE CIRM PRODUCT.
2 THEY CAME INTO OUR FIRST DISEASE TEAM TO DEVELOP THE
3 PRODUCT. WE'VE SUPPORTED TWO OF THE THREE CLINICAL
4 TRIALS. SO IF THIS TURNS OUT TO BE A MAJOR SUCCESS,
5 THIS WILL BE A REAL FEATHER FOR CIRM. WE'VE BEEN
6 WITH THEM ALL THE WAY. SO I'M OPTIMISTIC.

7 DR. STEWARD: SO IF YOU COULD PRESENT THIS
8 NEXT ONE.

9 DR. JORGENSON: THE NEXT APPLICATION WAS
10 AN APPLICATION TO CLIN1, WHICH IS THE PRECLINICAL
11 PROGRAM, CLIN1-8363. THIS APPLICATION IS DEVELOPING
12 AN AUTOLOGOUS CD HEMATOPOIETIC STEM CELL TAKEN FROM
13 ARTEMIS-DEFICIENT SEVERE COMBINED IMMUNODEFICIENCY
14 PATIENTS OR ART SCID PATIENTS. THEY THEN MODIFY
15 THOSE CELLS WITH A GENE THERAPY SO THAT THE CELLS
16 EXPRESS A CORRECTED COPY OF THE ARTEMIS GENE WHICH
17 IS THE DEFECT IN THESE PATIENTS.

18 THE GOAL OF THIS APPLICATION -- THE
19 INDICATION THAT THE ULTIMATE CLINICAL TRIAL WOULD BE
20 IN PATIENTS WITH ART SCID WHO LACK A MATCHED SIBLING
21 TRANSPLANT DONOR OR WHO HAVE FAILED ALLOGENEIC
22 TRANSPLANT. SO FOR THIS PARTICULAR INDICATION, THIS
23 IS BASICALLY THE STANDARD OF CARE, BUT SOME
24 PATIENTS, AS WE ALL KNOW, ARE ON A WAIT LIST AND DO
25 NOT HAVE ACCESS TO A MATCHED DONOR. SO THIS IS THE

BARRISTERS' REPORTING SERVICE

1 ISSUE THAT THIS APPLICATION IS TRYING TO ADDRESS.

2 THE GOAL OF THIS APPLICATION IS TO
3 COMPLETE A PRECLINICAL RESEARCH ACTIVITY AND SUBMIT
4 AN IND TO CONDUCT THE DESCRIBED CLINICAL TRIAL.

5 THE PROPOSED MAJOR ACTIVITIES ARE TO
6 MANUFACTURE A SUFFICIENT QUANTITY OF THE PRECLINICAL
7 VECTOR, TO CONDUCT THE TOXICITY AND EFFICACY
8 STUDIES, AND TO MANUFACTURE A CLINICAL GRADE VECTOR
9 FOR THE SUBSEQUENT CLINICAL TRIAL.

10 SECOND, THEY WANT TO COMPLETE NONCLINICAL
11 TOXICITY STUDIES AND DEMONSTRATE THE ABILITY TO
12 MANUFACTURE TRANSDUCED HUMAN CELLS AT CLINICAL
13 SCALE.

14 AND THIRDLY, THEY WANT TO COMPLETE ALL THE
15 NONCLINICAL EFFICACY STUDIES THAT WILL BE REQUIRED
16 TO SUPPORT THE IND FILING.

17 THEY HAVE REQUESTED \$4.3 MILLION TO DO
18 THESE ACTIVITIES. AS THIS IS A CLIN1 FROM A
19 NONPROFIT ORGANIZATION, THEY DO NOT PROVIDE
20 CO-FUNDING.

21 THIS APPLICATION PASSED THE BUDGET REVIEW
22 BEFORE IT WAS FORWARDED TO THE GRANTS WORKING GROUP.
23 THIS APPLICATION WAS REVIEWED TWICE BY THE GRANTS
24 WORKING GROUP. THE SECOND REVIEW WAS THE FEBRUARY
25 23D REVIEW WHERE IT RECEIVED A SCORE OF 1,

BARRISTERS' REPORTING SERVICE

1 INDICATING THE REVIEW PANEL FELT IT HAD EXCEPTIONAL
2 MERIT AND WARRANTS FUNDING. EIGHT MEMBERS OF THE
3 GWG VOTED FOR A SCORE OF 1, SIX VOTED FOR A SCORE OF
4 2, AND ONE VOTED FOR A SCORE OF 3. THE CIRM TEAM
5 RECOMMENDATION IS TO FUND IN THE AMOUNT REQUESTED BY
6 THE APPLICANT OF \$4.3 MILLION, CONCURRING WITH THE
7 GWG RECOMMENDATION.

8 AS WITH THE PREVIOUS APPLICATION, WE TOOK
9 THE VOTE ON THE REVIEW PROCESS, AND ALL MEMBERS OF
10 THE GWG VOTED UNANIMOUSLY IN FAVOR OF THE FIRST
11 VOTE, AND ALL ICOC MEMBERS VOTED UNANIMOUSLY IN
12 FAVOR OF THE SECOND VOTE.

13 I'M HAPPY TO TAKE QUESTIONS OR TO TURN
14 OVER TO OS FOR FURTHER DISCUSSION.

15 DR. STEWARD: ANY QUESTIONS? DR. PANETTA.

16 MR. PANETTA: THANK YOU. THIS WAS ONE
17 WHERE I HAVE TO ADMIT I'M COMPLETELY IN THE DARK AS
18 A LAYPERSON ABOUT WHAT AN ARTEMIS GENE IS. SO MAYBE
19 THERE ARE OTHERS, BUT IF YOU HELP ME UNDERSTAND.

20 DR. JORGENSON: IT'S A GENE DEFECT THAT
21 MEANS YOUR HEMATOPOIETIC SYSTEM DOESN'T DEVELOP
22 APPROPRIATELY SO THAT YOU ARE UNABLE TO MOUNT A
23 NORMAL IMMUNE RESPONSE. SO THESE PATIENTS ARE
24 UNABLE TO FIGHT OFF INFECTIONS. THEIR IMMUNE SYSTEM
25 DOESN'T RESPOND APPROPRIATELY. IT'S A SPECIFIC

BARRISTERS' REPORTING SERVICE

1 MUTATION IN THAT GENE. SO CORRECTION OF THAT GENE
2 CAN RESOLVE THE PROBLEM PROVIDED THAT THE
3 TRANSPLANTED CELLS ARE THEN ABLE TO DIFFERENTIATE
4 INTO ALL IMMUNE TYPES THAT ARE NEEDED TO MOUNT
5 APPROPRIATE IMMUNE RESPONSES.

6 MS. LAPORTE: MY QUESTION IS I REALIZE
7 THIS IS A PRECLINICAL AWARD, BUT IN THE COMMENTS
8 THERE WAS A COMMENT ABOUT THE ENSUING CLINICAL TRIAL
9 AND A CONCERN ABOUT INSUFFICIENT PATIENTS FOR SUCH A
10 TRIAL. SO MY CONCERN IS NO POINT IN FUNDING
11 PRECLINICAL WORK IF THE CLINICAL TRIAL IS GOING TO
12 BE UNENROLLABLE.

13 DR. JORGENSON: THAT WAS THE PRIMARY
14 REASON FOR THE SPLIT VOTE THAT YOU SAW. AND SOME
15 MEMBERS FELT THAT THIS WAS AN ISSUE THAT COULD BE
16 RESOLVED OVER THE COURSE OF THE AWARD AND IT WOULD
17 BE APPROPRIATE TO RESOLVE IT OVER THE COURSE OF THE
18 AWARD. AND OTHER REVIEWERS WOULD HAVE LIKED TO SEE
19 THE APPLICANT ADDRESS SOME OF THOSE ISSUES OR
20 DISCUSS SOME OF THOSE ISSUES BEFORE RECOMMENDING
21 FUNDING.

22 MS. LAPORTE: SOMETIMES THAT'S AN
23 ADDRESSABLE CONCERN.

24 DR. JORGENSON: I THINK THERE WASN'T
25 BECAUSE THIS WASN'T A PROPOSAL FOR A CLINICAL TRIAL.

BARRISTERS' REPORTING SERVICE

1 THIS WAS A PRECLINICAL PROPOSAL. THERE JUST WASN'T
2 SUFFICIENT -- THIS IS AN EXTREME ORPHAN DISEASE, SO
3 THAT'S WHERE THE CONCERN COMES FROM. AND THERE
4 WASN'T SUFFICIENT INFORMATION IN THE APPLICATION TO
5 MAKE A DETERMINATION AS TO WHETHER OR NOT THIS TEAM
6 WOULD BE ABLE TO ENROLL THE TRIAL. SOME REVIEWERS
7 FELT THAT WAS SOMETHING THAT COULD BE TAKEN CARE OF
8 DURING THE COURSE OF THE AWARD AND OTHERS WANTED TO
9 SEE IT ADDRESSED BEFORE RECOMMENDING IT.

10 DR. STEWARD: OTHER QUESTIONS BEFORE WE
11 ENTERTAIN A MOTION?

12 DR. BURTIS: COULD YOU EXPAND ON YOUR
13 COMMENT ABOUT EXTREME ORPHAN DISEASE? WHAT FRACTION
14 OF SCID CASES ARE ASSOCIATED WITH ARTEMIS MUTATIONS?
15 AND IS THERE A PARTICULAR -- IS THERE ANYTHING ELSE
16 YOU CAN EXPLAIN ABOUT IT?

17 DR. JORGENSON: I'M NOT GOING TO BE ABLE
18 TO ANSWER THAT QUESTION. I COULD MAYBE COME BACK
19 AND ANSWER IT, BUT I'M NOT GOING TO BE ABLE TO
20 ANSWER IT OFF THE TOP OF MY HEAD. IT'S PROBABLY IN
21 THE APPLICATION. I CAN GET THAT FOR YOU.

22 DR. STEWARD: OTHER QUESTIONS? ACTUALLY I
23 JUST WANTED TO MAKE CLEAR BEFORE WE TAKE THE MOTION
24 THAT THIS WAS A SPLIT VOTE BY THE GRANTS WORKING
25 GROUP. I JUST WANT TO CLARIFY FOR THE BOARD BUT

BARRISTERS' REPORTING SERVICE

1 ACTUALLY FOR THE PUBLIC AS WELL JUST SO WE'RE CLEAR.
2 THE STATEMENT AT THE BOTTOM HERE, ALL MEMBERS VOTED
3 UNANIMOUSLY IN FAVOR OF ONE. THAT MEANS THE
4 STATEMENT NO. 1 AND NOT A SCORE OF ONE. SO JUST TO
5 CLARIFY IT IS A SPLIT VOTE.

6 SO DO WE HAVE A MOTION?

7 MR. JUELSGAARD: I'LL MOVE APPROVAL.

8 DR. STEWARD: DO WE HAVE A SECOND?

9 MR. ROWLETT: THIS IS AL ROWLETT ON THE
10 PHONE. I WILL SECOND.

11 DR. STEWARD: THANK YOU. ANY FURTHER
12 DISCUSSION?

13 MR. JUELSGAARD: SO JUST TO FOLLOW UP ON
14 THE QUESTION THAT KATHY ASKED ABOUT NUMBER OF
15 ENROLLABLE PATIENTS AND THE CRITERIA THAT ARE
16 ESTABLISHED WHEN PEOPLE -- AND I REALIZE THIS IS A
17 PRECLINICAL STUDY, BUT EVEN SO, IT'S SORT OF
18 FRUITLESS TO DO A PRECLINICAL STUDY IF, AT THE END
19 OF THE DAY, YOU DON'T HAVE A CLINICAL POPULATION TO
20 TEST ON. SO I ASSUME, THEN, WE DON'T -- OR WHAT IS
21 THE STATUS OF ASKING THAT QUESTION OR ASKING FOR AN
22 ANSWER TO THAT QUESTION IN THE APPLICATION SUBMITTED
23 FOR PRECLINICAL FUNDING?

24 DR. JORGENSON: SO THE STATEMENT THAT YOU
25 MADE IS EXACTLY WHY REVIEWERS WERE CONCERNED ABOUT

BARRISTERS' REPORTING SERVICE

1 IT, FOR THE REVIEWERS THAT VOTED FOR A SCORE OF 2.
2 THE REVIEWERS THAT VOTED FOR A SCORE OF 1 FELT THAT
3 WE KNOW THIS IS AN ISSUE. THIS IS GOING TO BE
4 PROVIDED BACK TO THE APPLICANT. CIRM KNOWS THIS IS
5 AN ISSUE, AND WE CAN WORK WITH THEM TO BUILD
6 COLLABORATIONS WITH OTHER CENTERS AND BUILD A
7 CLINICAL PROTOCOL THAT IS, IN FACT, ENROLLABLE.
8 IT'S SOMETHING THAT THEY WOULD HAVE THE TWO-YEAR
9 AWARD PERIOD TO WORK TOWARDS. SO IT JUST FELL DOWN
10 TO WHETHER OR NOT REVIEWERS THOUGHT THAT WAS THE
11 MOST APPROPRIATE WAY TO DEAL WITH THE FACT THAT THIS
12 WILL BE A DIFFICULT TRIAL TO ENROLL OR WHETHER
13 REVIEWERS WANTED TO SEE THE APPLICANT DISCUSS THAT
14 BEFORE RECOMMENDING THE APPLICATION.

15 MR. JUELSGAARD: SO CAN I ASK CIRM'S
16 MANAGEMENT'S VIEW ON THAT PARTICULAR ISSUE?

17 DR. JORGENSON: THE CIRM RECOMMENDATION IS
18 TO FUND THE APPLICATION. SO IT'S SOMETHING THAT WE
19 THINK WE CAN WORK WITH THE TEAM TO TRY TO ADDRESS.

20 DR. MILLS: MAY I TALK?

21 DR. STEWARD: NO. SORRY. OF COURSE.

22 DR. MILLS: I THINK ONE OF THE THINGS I
23 THINK IT'S IMPORTANT TO UNDERSTAND AS WE MOVE
24 FORWARD IS CIRM'S ROLE IN THIS. WITH REGARDS TO
25 CIRM'S RECOMMENDATION, CIRM IS NOW MORE THAN EVER

BARRISTERS' REPORTING SERVICE

1 ADAMANT ABOUT IT'S A PROCESS RUNNING AGENCY, IT'S
2 NOT AN ADJUDICATION AGENCY, WHICH MEANS WE TRY TO
3 NOT LET ANY PERSONAL BIAS OR FEELINGS WE HAVE COME
4 IN AND INFLUENCE DECISIONS ONE WAY OR THE OTHER. WE
5 HAVE A GRANTS WORKING GROUP THAT'S SET UP AND
6 DESIGNED BY THE PROPOSITION TO DO THAT THAT'S
7 INDEPENDENT AND FREE OF BIAS.

8 OUR RECOMMENDATION STEMS AROUND WAS THERE
9 A PROBLEM WITH THE REVIEW? WAS THERE SOME PROBLEM
10 WITH THE PROCESS? IS THERE SOMETHING SORT OF
11 EXTRAORDINARY THAT THE PROCESS COULDN'T HANDLE OR
12 DIDN'T HANDLE THAT WE SHOULD BRING TO YOUR
13 ATTENTION? SO THAT'S WHERE OUR RECOMMENDATION COMES
14 FROM, NOT ARE WE ALSO ACTING AS GWG MEMBERS AND
15 ADJUDICATING THIS. THAT ULTIMATELY WILL BE A VERY
16 GOOD AND HEALTHY THING FOR CIRM SO CIRM DOESN'T GET
17 INTO THE OVERINFLUENCING OR OVERBIASING. WE JUST
18 WANT TO RUN A FAIR PROCESS. AND SO WHEN WE LOOK AT
19 THIS AND WE LOOK AT THE SCORE, OUR RECOMMENDATION TO
20 FUND, OUR RECOMMENDATION IS TO CONCUR WITH THE GWG
21 THAT A FAIR PROCESS WAS RUN AND THE OUTCOME WAS WHAT
22 THE PROCESS SAID IT SHOULD BE. DOES THAT MAKE
23 SENSE?

24 MR. JUELSGAARD: THIS IS ACTUALLY A
25 QUESTION FOR BOTH DR. STEWARD AND MR. SHEEHY. SO IN

BARRISTERS' REPORTING SERVICE

1 THE PAST WE'VE HAD TWO SORTS OF REVIEWS. ONE IS THE
2 GWG REVIEW OF THE SPECIFIC SCIENTIFIC RATIONALE
3 THAT'S BEING PRESENTED, AND THE OTHER IS WHAT WAS
4 CALLED A PROGRAMMATIC REVIEW, WHICH WAS LEFT TO THIS
5 ORGANIZATION. AND SO I ASKED AN EARLIER QUESTION
6 ABOUT THE TRIAL THAT RETURNED \$17 MILLION AND ABOUT
7 PROGRAMMATIC REVIEW. AND I HAVEN'T HEARD THAT TERM
8 USED RECENTLY, AND IT'S NOT CLEAR TO ME WHETHER
9 SUFFICIENT ENROLLABLE PATIENTS FOR A FUTURE CLINICAL
10 TRIAL IS A PROGRAMMATIC ISSUE OR NOT. WHAT DO WE DO
11 THESE DAYS ABOUT PROGRAMMATIC REVIEW? AND IT'S
12 ACTUALLY A QUESTION FOR THESE TWO GENTLEMEN.

13 DR. STEWARD: WELL, I'LL ANSWER AND I
14 GUESS JEFF COULD COMMENT BECAUSE THIS IS NOT
15 DIRECTLY RELATED TO THIS GRANT. IS THAT FAIR?

16 MR. HARRISON: CORRECT.

17 DR. STEWARD: I THINK THAT THE WAY I WOULD
18 PHRASE IT IS THAT, ALTHOUGH WE DON'T REALLY CALL IT
19 A PROGRAMMATIC REVIEW PER SE, THAT IS REALLY WHAT
20 WE'RE SORT OF DOING AT THIS POINT. AND THAT THESE
21 ARE WHERE EXACTLY THESE KINDS OF CONSIDERATIONS ARE
22 COMING UP, BUT WE DON'T DO THE KIND OF THING IN
23 EXACTLY THE SAME FRAMEWORK THAT WE DID IN THE PAST.
24 JEFF, DO YOU WANT TO ADD TO THAT?

25 MR. SHEEHY: YEAH. I WOULD CONCUR WITH

BARRISTERS' REPORTING SERVICE

1 DR. STEWARD. THE FORMAL PROGRAMMATIC REVIEW AT THE
2 GRANTS WORKING GROUP NO LONGER EXISTS, AND SO
3 PROGRAMMATIC CONSIDERATIONS COME INTO PLAY, AS I
4 UNDERSTAND IT, WITHIN THE APPLICATION REVIEW
5 SUBCOMMITTEE.

6 DR. STEWARD: SO COULD I JUST ASK YOU, I'M
7 NOT SURE, RANDY OR BECKY. A SCORE OF 2 OFTEN MEANS
8 THAT THE ONES WHO WERE VOTING ARE ASKING FOR
9 SOMETHING IN PARTICULAR TO COME BACK. AND I JUST
10 WAS WONDERING IF YOU COULD UNPACK THAT A LITTLE BIT,
11 IF THERE WERE SPECIFIC THINGS RELATED TO THIS FAIRLY
12 SIGNIFICANT CONCERN THAT WAS ADDRESSED IN THE
13 REVIEWS.

14 DR. JORGENSON: THIS APPLICATION REVIEW
15 WAS FAIRLY CLEAR THERE WAS MINOR CONCERNS RAISED,
16 BUT THE REVIEWERS THAT RAISED THE ISSUE WERE PRETTY
17 CLEAR THEIR MAJOR ISSUE WAS THE CLINICAL TRIAL.
18 IT'S AN ORPHAN INDICATION. THEY WERE UNSURE FROM
19 THE INFORMATION PROVIDED IN THE APPLICATION WHETHER
20 OR NOT THE TRIAL WOULD BE ENROLLABLE. AND AS MANY
21 OF YOU HAVE SAID, IF THE TRIAL IS NOT ENROLLABLE,
22 THAT'S WHAT THIS AWARD IS TO DO. SO THAT REALLY WAS
23 THE ISSUE. AND I DON'T KNOW WHAT ELSE I CAN SAY
24 BESIDES EIGHT MEMBERS FELL ON THE SIDE THAT THEY
25 COULD FIX IT DURING THE COURSE OF THE AWARD OR

BARRISTERS' REPORTING SERVICE

1 ADDRESS IT AND PREPARE FOR IT DURING THE COURSE OF
2 THE AWARD, AND SIX OTHER MEMBERS WOULD HAVE LIKED TO
3 HAVE SEEN IT ADDRESSED BEFORE IT RECEIVED A FUND
4 RECOMMENDATION.

5 DR. STEWARD: SO THAT WAS THE SPECIFIC
6 THING THAT THEY WANTED TO HEAR MORE ABOUT.

7 MR. PANETTA: I JUST WOULD LIKE TO BE SURE
8 THAT WE'RE CLEAR BECAUSE I'M SURE THAT FOR THE
9 PATIENTS WHO SUFFER AS A RESULT OF THIS ORPHAN
10 DISEASE, THAT THIS COULD BE VERY, VERY SIGNIFICANT
11 TO THEM. IS THE ISSUE THAT THE APPLICANT DID NOT
12 MAKE IT CLEAR RELATIVE TO THE NUMBER OF PATIENTS
13 THAT COULD BE ENROLLED IN THE TRIAL, OR THAT THE GWG
14 IS CONCERNED THAT THERE ARE NOT ENOUGH PATIENTS TO
15 ENROLL IN THE TRIAL?

16 DR. JORGENSON: IT'S AN ORPHAN INDICATION
17 WHERE ENROLLING THE TRIAL WILL BE CHALLENGING
18 BECAUSE OF THE LACK OF NUMBER OF PATIENTS AND
19 PARTIALLY BECAUSE WE DON'T GO INTO THE SAME LEVEL OF
20 DETAIL IN THE DESCRIPTION OF HOW THEY'RE GOING TO
21 ENROLL THE CLINICAL TRIAL. IN THE PRECLINICAL
22 AWARD, THERE WAS NOT AS MUCH DETAIL ON HOW THEY
23 WOULD ENROLL THE TRIAL. BECAUSE IT'S GOING TO BE A
24 PARTICULARLY CHALLENGING TRIAL TO ENROLL, THERE WAS
25 MORE CONCERN AT THIS STAGE THAN THERE MIGHT HAVE

BARRISTERS' REPORTING SERVICE

1 BEEN FOR A MYOCARDIAL INFARCT.

2 MR. PANETTA: JUST TO FOLLOW UP THEN, THE
3 APPLICANT COULD COME BACK AND CORRECT THAT
4 DEFICIENCY BY EXPLAINING HOW THEY WILL ENROLL
5 PATIENTS IN THE TRIAL, AND THEY COULD POTENTIALLY
6 ENROLL PATIENTS IN THE TRIAL. AND SO IT'S NOT
7 NECESSARILY THAT THE PATIENTS ARE NOT OUT THERE TO
8 BE ENROLLED IN THE TRIAL?

9 DR. JORGENSON: YES. IT'S THAT IT WILL
10 TAKE OPERATIONAL EXCELLENCE TO ENROLL THE TRIAL.

11 MR. JUELSGAARD: MR. PANETTA, JUST TO ADD
12 TO THAT, ONE OF THE CONSIDERATIONS OF THE GRANTS
13 WORKING GROUP, ONE OF THE CONCERNS WAS A REASONABLE
14 ASSESSMENT OF COMPETING TRIALS THAT MAY REDUCE
15 AVAILABILITY OF THOSE PATIENTS. SO IT'S NOT JUST
16 THE ENTIRE TRIAL GROUP. THIS IS BACK TO ONE WHERE
17 MONEY WAS RETURNED. IN ESSENCE, THOSE PATIENTS THAT
18 OTHERWISE WOULD HAVE ENROLLED IN THAT PHASE III
19 TRIAL ARE NOW BEING TREATED BY, I TAKE IT, IT'S
20 EITHER OPDIVO OR KEYTRUDA, IT'S SOMETHING THAT
21 TREATS METASTATIC MELANOMA. IN ANY EVENT, THAT'S
22 THE SAME ISSUE HERE. WHAT'S THE COMPETITION LIKE
23 AND WILL WE GET ENOUGH PATIENTS?

24 OBVIOUSLY IT'S A VERY IMPORTANT AND KEY
25 ISSUE. IT'S SOMETHING WE NEED TO THINK ABOUT IN THE

BARRISTERS' REPORTING SERVICE

1 FUTURE, AS WE HAVE THESE APPLICATIONS COME IN, JUST
2 ABOUT THE VIABILITY. IT'S NOT THAT I'M OPPOSED TO
3 THIS ONE, BUT IT'S JUST THAT I THINK THIS IS AN
4 IMPORTANT CONSIDERATION BECAUSE WE'VE NOW HAD ONE
5 WHERE MONEY HAS BEEN RETURNED, AND THIS ONE MAY FIND
6 ITSELF AT A DEAD END JUST BECAUSE THERE WON'T BE
7 ENOUGH PATIENTS AVAILABLE.

8 DR. WARE: THIS IS CARL WARE ONLINE. IF I
9 COULD ADD SOME INFORMATION TO THE DISCUSSION THAT
10 MIGHT BE HELPFUL.

11 DR. STEWARD: OKAY.

12 DR. WARE: SO SEVERE COMBINED
13 IMMUNODEFICIENCY DISEASE OCCURS IN ABOUT ONE IN
14 EVERY 50,000 BIRTHS. AND THE ARTEMIS MUTATION IS
15 QUITE PREVALENT IN THE NAVAJO AND APACHE INDIGENOUS
16 PEOPLES AND OCCURS AT A FREQUENCY OF 1 IN 2500. SO
17 WITH AN ESTIMATE LIKE THAT, I WOULD IMAGINE THAT
18 THERE WOULD BE AT LEAST A FEW PATIENTS THAT WOULD BE
19 ABLE TO BE ENROLLED OVER THE COURSE OF THE CLINICAL
20 TRIAL STUDY PERIOD.

21 DR. STEWARD: THANK YOU. OTHER QUESTIONS?
22 IF NOT, WE DO HAVE A MOTION AND A SECOND, SO TURN IT
23 OVER TO MARIA FOR ROLL CALL. I'M SORRY. PUBLIC
24 COMMENT. SEEING NONE, MARIA.

25 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

BARRISTERS' REPORTING SERVICE

1 DR. DULIEGE: NO.
2 MS. BONNEVILLE: DAVID HIGGINS.
3 DR. HIGGINS: YES.
4 MS. BONNEVILLE: STEVE JUELSGAARD.
5 MR. JUELSGAARD: YES.
6 MS. BONNEVILLE: KATHY LAPORTE.
7 MS. LAPORTE: NO.
8 MS. BONNEVILLE: LAUREN MILLER.
9 MS. MILLER: YES.
10 MS. BONNEVILLE: ADRIANA PADILLA.
11 DR. PADILLA: YES.
12 MS. BONNEVILLE: JOE PANETTA.
13 MR. PANETTA: YES.
14 MS. BONNEVILLE: FRANCISCO PRIETO. ROBERT
15 QUINT.
16 DR. QUINT: NO.
17 MS. BONNEVILLE: AL ROWLETT.
18 MR. ROWLETT: YES.
19 MS. BONNEVILLE: OS STEWARD.
20 DR. STEWARD: YES.
21 MS. BONNEVILLE: JONATHAN THOMAS.
22 CHAIRMAN THOMAS: YES.
23 MS. BONNEVILLE: ART TORRES.
24 MR. TORRES: AYE.
25 MS. BONNEVILLE: DIANE WINOKUR.

BARRISTERS' REPORTING SERVICE

1 MS. WINOKUR: YES.

2 MR. HARRISON: MOTION CARRIES.

3 DR. STEWARD: THANK YOU. BACK TO YOU,
4 JEFF.

5 MR. SHEEHY: I THINK WE'RE READY TO DO THE
6 TRANSLATION ROUND.

7 CHAIRMAN THOMAS: WE'RE GOING TO TAKE A
8 TEN-MINUTE BREAK.

9 MR. SHEEHY: I WAS GOING TO SUGGEST THAT.
10 YOU MUST BE PSYCHIC.

11 CHAIRMAN THOMAS: BETH MOVES AND SECONDS
12 FOR A TEN-MINUTE BREAK. NO NEED FOR A VOTE. WE'LL
13 RECONVENE IN TEN.

14 (A RECESS WAS TAKEN.)

15 CHAIRMAN THOMAS: COULD EVERYBODY START TO
16 CIRCLE BACK TO THEIR SEATS PLEASE. OKAY. WE ARE
17 GOING TO RESUME FOR MEMBERS ON THE PHONE. WE NOW
18 TURN TO ACTION ITEM NO. 10, CONSIDERATION OF
19 APPLICATIONS SUBMITTED IN RESPONSE TO THE
20 TRANSLATION RESEARCH PROGRAM ANNOUNCEMENT SO-CALLED
21 TRAN1 THROUGH 4. DR. THAKAR WILL PRESENT.

22 MR. SHEEHY: I'M SORRY. COULD WE HOLD FOR
23 A MINUTE BECAUSE WE HAVE THREE MEMBERS OF THE
24 APPLICATION REVIEW SUBCOMMITTEE WHO HAVEN'T
25 RETURNED? I THINK WE SHOULD PROBABLY HOLD.

BARRISTERS' REPORTING SERVICE

1 MS. LAPORTE, DR. STEWARD, AND MR. JUELSGAARD.

2 (PAUSE IN PROCEEDINGS.)

3 CHAIRMAN THOMAS: FOR THOSE ON THE PHONE,
4 WE'RE JUST WAITING FOR ANOTHER MEMBER OR TWO TO
5 RETURN HERE.

6 MR. SHEEHY: SO, PLEASE.

7 DR. THAKAR: THANK YOU, MR. CHAIRMAN,
8 MEMBERS OF THE BOARD. FOR YOUR CONSIDERATION TODAY
9 I WOULD LIKE TO PRESENT TO YOU THE RESULTS OF THE
10 VERY FIRST TRANSLATION RESEARCH PROGRAM AND ITS GWG
11 RECOMMENDATIONS.

12 MY NAME IS RAHUL THAKAR. I'M A MEMBER OF
13 THE CIRM TEAM.

14 MY PRESENTATION HAS TWO PARTS, JUST A
15 BRIEF INTRODUCTION OVER WHAT THE TRANSLATION
16 RESEARCH PROGRAM IS AND THEN THE RECOMMENDATIONS OF
17 THE GWG ITSELF FOR THE REVIEW THAT OCCURRED FEBRUARY
18 11TH THROUGH 12TH OF THE PREVIOUS MONTH.

19 THE PROGRAM OVERVIEW. THE OBJECTIVE OF
20 THE TRANSLATION RESEARCH PROGRAM IS QUITE
21 STRAIGHTFORWARD. IT IS TO SUPPORT PROMISING STEM
22 CELL-BASED PROJECTS THAT ACCELERATE THE COMPLETION
23 OF TRANSLATION STAGE ACTIVITIES NECESSARY FOR
24 ADVANCEMENT TO CLINICAL STUDY OR BROAD END USE. AS
25 A REMINDER, THIS PROGRAM WAS ACCEPTED BY THE BOARD

BARRISTERS' REPORTING SERVICE

1 IN ITS CONCEPTEED FORM IN JULY 2015, AND THIS IS
2 INDEED THE VERY FIRST REVIEW WE'VE HELD FOR THIS
3 PROGRAM.

4 AND AS ANOTHER REMINDER OF WHERE THIS
5 PROGRAM FITS IN THE GREATER CONTEXT OF THE CIRM 2.0
6 PIPELINE, WE TALK ABOUT CIRM AND CIRM 2.0 AND HAVING
7 ENGINES AND AIRPLANES, TRAINS, AND ENGINES. WE'RE
8 GOING TO USE THE TRAIN HERE. AS YOU CAN SEE,
9 TRANSLATION IS RIGHT IN THE MIDDLE BETWEEN OUR
10 CLINICAL AND OUR DISCOVERY PROGRAMS.

11 THE KEY THING TO NOTE HERE IS THAT THE
12 OUTPUT, WHATEVER THE EXPECTED OUTCOMES ARE OF THE
13 DISCOVERY PROGRAM, THEY ENTER INTO OUR TRANSLATION
14 PROGRAM. SIMILARLY, THE EXPECTED OUTCOMES OF OUR
15 TRANSLATION PROGRAM FEED DIRECTLY INTO OUR CLINICAL
16 PROGRAM. FOR EXAMPLE, A DISC2 OR DISCOVERY 2:
17 QUEST PROGRAM, WHICH INCIDENTALLY HAD ITS DEADLINE
18 YESTERDAY FOR APPLICATIONS, THAT WILL FEED DIRECTLY
19 INTO THE TRAN1, 2, 3, OR 4 TRACKS. SUCCESSFUL
20 COMPLETION OF THE TRAN1, 2, 3, OR 4 WILL FEED
21 DIRECTLY INTO CLIN1. AND DISCOVERY AND TRANSLATION
22 BOTH RUN TWICE A YEAR, AND THE CLINICAL PROGRAM RUNS
23 12 TIMES A YEAR OR ONCE A MONTH. THIS I BELIEVE TO
24 BE A VERY ELEGANT DESIGN, ELEGANT ENGINE, AND IT
25 ALLOWS US TO HAVE THE CONTINUOUS STREAM OF

BARRISTERS' REPORTING SERVICE

1 APPLICATIONS AND PROGRESS THAT WE HOPE TO DO.

2 SO LET'S GET INTO SOME OF THE DETAILS
3 ABOUT WHAT THE TRANSLATION PROGRAM ACTUALLY IS. SO
4 WHAT'S COMING INTO THE TRANSLATION PROGRAM? WELL,
5 THAT PROOF OF CONCEPT WITH A CANDIDATE PRODUCT.
6 THIS CANDIDATE PRODUCT CAN BE ONE OF FOUR THINGS: A
7 THERAPEUTIC OR TRAN1, AND THAT'S OUR CELL THERAPIES,
8 BIOLOGICS, SMALL MOLECULES, COMBINATION PRODUCTS;
9 THE DIAGNOSTIC TRACK OR TRAN2; THE MEDICAL DEVICE
10 ROUTE, WHICH IS TRAN3; AND THE TOOL ROUTE, WHICH IS
11 TRAN4.

12 ONE POINT TO KEEP IN MIND IS TRACKS OR
13 TRAN1, 2, AND 3, ARE ALL WHAT ONE COULD CONSIDER THE
14 REGULATED PATH. SO THAT THE EXPECTED OUTCOME IS A
15 PRE-IND OR PRESUBMISSION MEETING WITH THE FDA.
16 TRACK 4 OR TRAN4 OR THE TOOL ROUTE, THE EXPECTED
17 OUTCOME OF A SUCCESSFUL PROJECT IS THAT THE
18 APPLICANT OR THE GRANTEE AT THAT POINT IS READY TO
19 MOVE TO MANUFACTURING FOR BROAD END USE OR
20 COMMERCIALIZATION OF THAT PRODUCT.

21 ONE MORE ASPECT OF THE PROGRAM. SINCE
22 THERE'S DIFFERENT ROUTES, DIFFERENT PATHS, AS WE
23 APPROACH THE CLINICAL PROGRAM OR GOING THROUGH THE
24 TRANSLATION PROGRAM, THERE'S A DIFFERENT SET OF
25 ACTIVITIES. SO, THUS, THERE'S A DIFFERENT SET OF

BARRISTERS' REPORTING SERVICE

1 TIMELINES AND DIFFERENT ACTIVITIES. SO THERE'S
2 DIFFERENT DIRECT COSTS THAT HAVE BEEN LAID OUT IN
3 THE PROGRAM.

4 SO TRACK 1, TRAN1, THE THERAPEUTIC ROUTE,
5 THAT HAS UP TO 30 MONTHS AND \$5 MILLION FOR DIRECT
6 COSTS FOR BIOLOGICS, CELL THERAPIES, COMBINATION
7 PRODUCTS; 2.5 MILLION IN DIRECT COSTS FOR SMALL
8 MOLECULES. TRAN2, 3, AND 4, THE DIAGNOSTIC DEVICE
9 AND TOOL ROUTES, ALL HAVE A MAXIMUM OF 24 MONTHS.
10 AND AS YOU CAN SEE, THE BUDGET VARIES ACCORDING TO
11 THE ROUTE OF TRANSLATION AND DEVELOPMENT.

12 A FINAL SET OF POINTS TO KEEP IN MIND FOR
13 THE TRANSLATION REVIEW ITSELF. ALL THE PRODUCT
14 TYPES WERE ASSESSED TOGETHER. ALL APPLICATIONS WERE
15 ASSESSED TOGETHER. THERE WERE 30 APPLICATIONS. THE
16 REVIEW CRITERIA WERE THE SAME FOR ALL FOUR PRODUCT
17 TYPES. AND WHY DID WE DO THIS? WELL, THE GOAL OF
18 THE TRANSLATION RESEARCH PROGRAM AND ITS REVIEW WAS
19 TO IDENTIFY THE PROJECTS THAT WERE MOST LIKELY TO
20 ACHIEVE THE OBJECTIVE, AS I STATED EARLIER, OF THIS
21 PROGRAM IRRESPECTIVE OF THE PRODUCT TYPE OR CELL
22 TYPE OR ANYTHING LIKE THAT. IT'S WHAT IS THE BEST
23 SCIENCE, WHAT ARE THE MOST READY PROJECTS THAT ARE
24 GOING TO ACHIEVE THE OBJECTIVE OF THIS PROGRAM?

25 AND THE REVIEW CRITERIA. DID THE PROJECT

BARRISTERS' REPORTING SERVICE

1 HOLD THE NECESSARY SIGNIFICANCE AND POTENTIAL FOR
2 IMPACT? WAS THE RATIONALE SOUND? WAS THE PROJECT
3 WELL-PLANNED AND DESIGNED? AND FINALLY, WAS THE
4 PROJECT ITSELF FEASIBLE?

5 SO NOW THE GWG RECOMMENDATIONS. AS A
6 REMINDER, I BELIEVE, PLEASE CORRECT ME IF I'M WRONG,
7 JANUARY 2016 THE NEW SCORING SYSTEM FOR THE
8 DISCOVERY AND TRANSLATION PROGRAMS WAS APPROVED BY
9 THE ICOC. AND WHAT THE NEW SCORING SYSTEM ENTAILS
10 IS A TWO-TIER SYSTEM, A TIER I WHICH ENTAILS A SCORE
11 OF 85 TO 100, AND THIS SIGNIFIES A PROJECT THAT HAS
12 EXCEPTIONAL MERIT AND WARRANTS FUNDING IF FUNDS ARE
13 AVAILABLE. THE SECOND TIER OR TIER II ARE PROJECTS
14 THAT SCORE BETWEEN 1 TO 84. SO WE'RE USING A 1 TO
15 100 SCALE. AND TIER II SIGNIFIES PROJECTS THAT ARE
16 NOT RECOMMENDED FOR FUNDING.

17 ONE FINAL NOTE. APPLICATIONS ARE SCORED
18 BY ALL SCIENTIFIC MEMBERS OF THE GWG WHO ARE NOT IN
19 CONFLICT WITH THAT PARTICULAR APPLICATION.

20 SO THE GWG RECOMMENDED THE FOLLOWING. IN
21 TIER I WITH SCORES BETWEEN 85 TO 100, EXCEPTIONAL
22 MERIT AND WARRANT FUNDING IF FUNDS ARE AVAILABLE,
23 THERE ARE EIGHT PROJECTS, EIGHT APPLICATIONS, AND
24 THEIR BUDGETS SUM TO APPROXIMATELY \$39.7 MILLION.
25 IN TIER II ARE THE REMAINING 22 APPLICATIONS. THE

BARRISTERS' REPORTING SERVICE

1 GWG DEEMED THESE PROJECTS NOT RECOMMENDED FOR
2 FUNDING.

3 AS A REMINDER, DR. JORGENSON HAD A SIMILAR
4 SLIDE. THE SAME VOTE OCCURRED FOR PROCESS AT THE
5 TRAN REVIEW. JUST AS A REMINDER, THE FIRST VOTE IS
6 TO ALL MEMBERS OF THE GWG. WAS THE REVIEW
7 SCIENTIFICALLY RIGOROUS? WAS THERE SUFFICIENT TIME
8 FOR ALL VIEWPOINTS TO BE HEARD? AND DID THE SCORES
9 REFLECT THE RECOMMENDATION OF THE GWG.

10 ALL MEMBERS VOTED FOR THE FIRST VOTE, 20
11 TO ZERO. THE SECOND VOTE GOES TO THE ICOC PATIENT
12 ADVOCATE MEMBERS. WAS THE REVIEW CARRIED OUT IN A
13 FAIR MANNER, AND WAS IT FREE FROM UNDUE BIAS? AND
14 THE PATIENT ADVOCATE GWG MEMBERS VOTED UNANIMOUSLY
15 IN FAVOR OF 2 SIX TO ZERO.

16 FINALLY, THE CIRM TEAM RECOMMENDATIONS.
17 THE CIRM TEAM RECOMMENDS SEVEN APPLICATIONS IN TIER
18 I FOR A TOTAL BUDGET OF APPROXIMATELY \$36.8 MILLION
19 TO BE PLACED IN TIER I, AND THE REMAINING 22
20 APPLICATIONS THAT THE GWG PLACED IN TIER II TO
21 REMAIN IN TIER II AND BE PLACED IN TIER II FOR NOT
22 RECOMMENDED FOR FUNDING. AS YOU NOTE, THERE'S A
23 ASTERISK NEXT TO THE SEVEN. THE ASTERISK JUST
24 SIGNIFIES THAT THE CIRM TEAM RECOMMENDATION FOR
25 APPLICATION TRAN1-08522 IS IN TIER I, BUT DEFERRED

BARRISTERS' REPORTING SERVICE

1 FOR FURTHER REVIEW.

2 IF THERE ARE ANY QUESTIONS WITH RESPECT TO
3 THE REVIEW, I'D LOVE TO ANSWER THEM.

4 MR. SHEEHY: DR. THAKAR, COULD YOU JUST
5 GIVE A LITTLE BIT MORE CLARITY ON THE DEFERRAL? IS
6 THAT SOMETHING -- JUST SO WE HAVE -- WHAT'S THE VIEW
7 OF THE APPLICANT? IS THE APPLICANT DEFERRING IT?

8 DR. MILLS: SO IMPORTANT TO NOTE HERE, THE
9 DEFERRAL IS THE DEFERRAL OF OUR, CIRM'S,
10 RECOMMENDATION TO THE ICOC ON WHAT TO DO. AND THIS
11 COMES ABOUT AS ONE OF THOSE EXTRAORDINARY SITUATIONS
12 WHERE SHORTLY AFTER THE GWG MADE A RECOMMENDATION TO
13 FUND THIS, THIS WAS IN THE FUNDABLE CATEGORY, THE
14 PARENT OR THE 1.0 COMPOUND OF THE DRUG IN QUESTION,
15 WHICH WAS CITED HEAVILY IN THE APPLICATION AS BEING
16 SIGNIFICANT TO THE OVERALL SUCCESS OF THIS PROGRAM
17 BECAUSE OF ITS BREAKTHROUGH STATUS AND BECAUSE IT
18 WAS IN A PHASE III PIVOTAL TRIAL AND EXPECTED TO
19 DEMONSTRATE EARLY PROOF OF CONCEPT OF THIS, THE
20 PROGRAM WAS ACTUALLY TERMINATED BY THE PARENT ENTITY
21 FOR FUTILITY AND THE TRIAL WAS SHUT DOWN AND THE
22 PROGRAM WAS ENDED.

23 SO BECAUSE OF THAT INFORMATION THAT CAME
24 OUT AFTERWARDS AND BECAUSE WHAT WE DIDN'T WANT TO DO
25 IS MAKE A RECOMMENDATION TO THE BOARD THAT COULDN'T

BARRISTERS' REPORTING SERVICE

1 BE UNDONE, COULDN'T BE UNFUNDED ONCE THE
2 RECOMMENDATION WAS MADE, WE TALKED WITH THE
3 APPLICANT AND THE APPLICANT AGREED TO HAVE THEIR
4 APPLICATION DEFERRED SO THAT ALL THE INFORMATION
5 SURROUNDING THE TRIAL AND ALL OF THE OTHER PERTINENT
6 FACTS COULD BE ASSESSED, AND THEN WE'LL COME BACK TO
7 THE BOARD WITH OTHER RECOMMENDATION BASED ON THAT
8 NEW INFORMATION.

9 MR. SHEEHY: SO, MR. HARRISON, SO DO WE
10 NEED TO TAKE ACTION ON THIS APPLICATION, OR CAN WE
11 JUST ASSUME THAT IT'S NOT INCLUDED IN ANY OF THE
12 MOTIONS THAT WE MAKE?

13 MR. HARRISON: THE LATTER. IT'S NOT
14 PRESENTED TO YOU FOR YOUR CONSIDERATION. SO THE
15 ONLY THING I WOULD RECOMMEND IS, IF YOU APPROVE ALL
16 OF THE APPLICATIONS IN TIER I, THAT YOU EXCLUDE THIS
17 PARTICULAR APPLICATION GIVEN THE FACT THAT IT HAS
18 BEEN DEFERRED.

19 MR. SHEEHY: ANY QUESTIONS ON THIS FOR DR.
20 MILLS?

21 MR. JUELGAARD: YES. IF YOU GO TO THE
22 TRANSLATION RESEARCH PROGRAM SUMMARIES, WHICH
23 FOLLOWS THIS PRESENTATION, WHAT WAS PROVIDED TO US,
24 WHICH IS SORT OF THE COVER SHEET FOR ALL OF THESE,
25 YOU WILL NOTICE OR AT LEAST I NOTICED THAT THERE ARE

BARRISTERS' REPORTING SERVICE

1 IN SOME CASES 13 REVIEWERS, IN SOME CASES 14
2 REVIEWERS, AND IN SOME CASES 15 REVIEWERS. AND I'M
3 CURIOUS AS TO WHY WE HAVE A DIFFERENT NUMBER OF
4 REVIEWERS AMONGST THESE DIFFERENT PROGRAMS. WHY
5 THAT RESULT?

6 DR. THAKAR: IT'S AN EXCELLENT QUESTION.
7 FOR THAT COUNT, I GUESS, IT WILL NEVER EXCEED 15 AS
8 THERE ARE 15 SCIENTIFIC MEMBERS OF THE GWG. IF YOU
9 SEE A NUMBER LESS THAN THAT, CHANCES ARE IT'S DUE TO
10 A CONFLICT ON THE APPLICATION.

11 MR. JUELSGAARD: ALL RIGHT. THANKS.

12 MR. SHEEHY: SO ARE THERE ANY OTHER
13 QUESTIONS BEFORE I START TAKING MOTIONS? SO THE
14 FIRST MOTION I WOULD TAKE IS IS THERE A MOTION TO
15 REMOVE ANY APPLICATION FROM TIER I? OKAY.

16 SO IS THERE A MOTION TO MOVE ANY -- IS
17 THERE A MOTION TO MOVE ANY APPLICATION FROM TIER II
18 INTO TIER I?

19 DR. HIGGINS: I'D LIKE TO MOVE THAT THE
20 BOARD APPROVE FUNDING FOR APPLICATION 08468, WHICH
21 IS TITLED "AUTOLOGOUS CELL THERAPY FOR PARKINSON'S
22 DISEASE USING IPSC-DERIVED DA NEURONS."

23 MR. SHEEHY: IS THERE A SECOND FOR THAT
24 MOTION?

25 MR. PANETTA: SECOND THAT.

BARRISTERS' REPORTING SERVICE

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MR. SHEEHY: SECOND BY MR. PANETTA.

IS THERE SOMEONE ON THE CIRM TEAM THAT CAN
KIND OF LEAD US THROUGH A DISCUSSION OF THIS
APPLICATION?

DR. MILLS: TO BE CLEAR, WE CAN LEAD YOU
THROUGH THE SUMMARY OF THE GWG AND ANSWER QUESTIONS
ABOUT THE PROCESS.

MR. SHEEHY: THAT'S FINE.

DR. THAKAR: THIS IS THE PUBLIC REVIEW
SUMMARY FOR APPLICATION NO. TRAN1-08468. THE TITLE
AS WRITTEN BY THE APPLICANT, THE "AUTOLOGOUS CELL
THERAPY FOR PARKINSON'S DISEASE USING IPSC-DERIVED
DA NEURONS." THE TRANSLATIONAL CANDIDATE, AS
DESCRIBED BY THE APPLICANT, IT'S AN AUTOLOGOUS
DOPAMINERGIC NEURON DERIVED FROM PATIENT-SPECIFIC
INDUCED PLURIPOTENT STEM CELLS. THE AREA OF IMPACT,
PARKINSON'S DISEASE. AND THE MECHANISM OF ACTION,
AS REPORTED BY THE APPLICANT, THE PROPOSED CANDIDATE
IS INTENDED TO REPLACE THE LOST DA OR DOPAMINERGIC
NEURONS IN THE BRAINS OF PARKINSON'S DISEASE
PATIENTS. IT IS ESTIMATED THAT BY THE TIME PATIENTS
ARE DIAGNOSED WITH PARKINSON'S DISEASE, THEY'VE
ALREADY LOST OVER 50 PERCENT OF THEIR DA NEURONS IN
THEIR BRAINS.

EARLIER STUDIES USING FETAL TISSUE

BARRISTERS' REPORTING SERVICE

1 DEMONSTRATED PROOF OF PRINCIPLE FOR CELL REPLACEMENT
2 THERAPY. WE WILL USE HIGHLY QUALIFIED, WE BEING THE
3 APPLICANT, PATIENT-SPECIFIC DA NEURONS TO ELIMINATE
4 THE NEED FOR IMMUNOSUPPRESSION. THE UNMET MEDICAL
5 NEED, TO SUMMARIZE, IS FOR PARKINSON'S DISEASE.

6 THE MAJOR ACTIVITIES THAT THE APPLICANT
7 PROPOSES, IT IS TO ASSESS IN VIVO BEHAVIOR WITH A
8 DOSING STUDY, COMBINATION TUMOR BIODISTRIBUTION, AND
9 TOXICITY STUDIES, AND CELL DELIVERY USING A LARGE
10 ANIMAL MODEL.

11 SECOND, TO CHARACTERIZE COMPARABILITY
12 BETWEEN PATIENT CELL LINES, DETERMINE THE FINAL
13 PRODUCT, AND DEVELOP END PROCESS AND RELEASE
14 TESTING. AND THE FINAL ACTIVITY, TRANSFER
15 TECHNOLOGIES, PROTOCOLS, AND CELLS TO A CGMP
16 FACILITY FOR BANKING AND CELL PRODUCTION UNDER THOSE
17 CGMP CONDITIONS.

18 GO AHEAD AND MOVE TO THE GRANTS WORKING
19 GROUP. THE GRANTS WORKING GROUP SCORED THIS
20 APPLICATION WITH A 70. THE MEDIAN WAS A 70 AS WELL.
21 THE STANDARD OF DEVIATION WAS 5. THE HIGHEST SCORE
22 GIVEN TO THIS APPLICATION WAS AN 80, THE LOWEST WAS
23 A 60, AND 14 MEMBERS OF THE SCIENTIFIC GWG PORTION
24 OF THE PANEL VOTED. AND THEN THE OTHER THING TO
25 NOTE, JUST AS THE GWG VOTED, ZERO OF THE SCIENTIFIC

BARRISTERS' REPORTING SERVICE

1 MEMBERS VOTED IT IN TIER I BETWEEN A SCORE OF 85 AND
2 100. THE 14 MEMBERS WHO SCORED PLACED IT SOMEWHERE
3 BETWEEN 1 AND 84 IN TIER II.

4 THIS PART IS A LITTLE NEW. TO DESCRIBE
5 IT, THE SCORE INFLUENCES. THIS PART BASICALLY
6 SIGNIFIES THE FOUR MAJOR REVIEW CRITERIA AND WHETHER
7 A PARTICULAR REVIEWER BELIEVED THAT CRITERION TO BE
8 A POSITIVE, NEGATIVE, OR NO IMPACT NEUTRAL
9 INFLUENCE. IF ONE IS TO LOOK AT THE POTENTIAL OF
10 OUR IMPACT FOR THIS APPLICATION, EIGHT REVIEWERS
11 GAVE IT A POSITIVE INFLUENCE, TWO GAVE IT A
12 NEGATIVE, FOUR GAVE IT A NEUTRAL.

13 IS THE RATIONALE SOUND? SEVEN REVIEWERS
14 GAVE IT A POSITIVE INFLUENCE, THREE A NEGATIVE, FOUR
15 GAVE IT A NEUTRAL.

16 IS THE PROPOSAL WELL-PLANNED AND DESIGNED?
17 HERE, TWO REVIEWERS GAVE IT A POSITIVE INFLUENCE,
18 NINE GAVE IT A NEGATIVE INFLUENCE, AND THREE GAVE IT
19 A NEUTRAL INFLUENCE.

20 AND FINALLY, THE FEASIBILITY OF THE
21 PROPOSAL. ONE REVIEWER GAVE IT A POSITIVE
22 INFLUENCE, SIX A NEGATIVE, AND SEVEN A NEUTRAL
23 INFLUENCE.

24 AS WE APPROACH THE FINAL PART OF THIS
25 SUMMARY, IT'S THE REVIEWER COMMENTS. THESE COMMENTS

BARRISTERS' REPORTING SERVICE

1 WERE BY AND LARGE TAKEN FROM THE REVIEWERS AS WELL
2 AS THE PATIENT ADVOCATE ASSIGNED TO THE APPLICATION
3 FROM THEIR CRITIQUES AS WELL AS THEIR IN-PERSON
4 SCORING. AS THE DISCUSSION OVER AN APPLICATION
5 OCCURRED, WE ALWAYS ASK THE REVIEW PANEL TO PLACE
6 THEIR FINAL SCORE. AND FOR THE ASSIGNED REVIEWERS
7 WHO SCORED, THERE'S ONE ADDITIONAL REQUEST NOW, AND
8 THAT'S TO GIVE A SERIES OF STRENGTHS, CONCERNS, OR
9 JUST ADDITIONAL COMMENTS, SUGGESTIONS,
10 RECOMMENDATIONS TO EACH APPLICATION.

11 AND WHAT WE HAVE HERE IS A SYNTHESIS OF
12 THE SET OF COMMENTS THAT WERE PLACED FOR EACH
13 APPLICATION. AND THIS ONE IN PARTICULAR SPANS TWO
14 PAGES. IN CERTAIN CASES, COMMENTS WERE MADE
15 MULTIPLE TIMES. THESE COMMENTS ARE SYNTHESIZED INTO
16 ONE DISCRETE STATEMENT.

17 TO BEST SUMMARIZE IT, THE TEAM WAS
18 CONSIDERED TO BE WELL-SUITED FOR THE CELL PRODUCTION
19 AND THAT COMPONENT OF THE STUDY. THE PROJECT DOES
20 HAVE SIGNIFICANCE, AND IT HAS A SUFFICIENT AMOUNT OF
21 IMPACT. HOWEVER, THERE'S A NUMBER OF CONCERNS. THE
22 KEY CONCERN IS HIGHLIGHTED IN THE FIRST BULLET. AND
23 TO QUOTE THE SUMMARY, "ALTHOUGH THE STRATEGY IS
24 PROMISING, THE PROPOSAL IS NOT READY FOR
25 TRANSLATION. IT IS MISSING KEY METHODOLOGICAL

BARRISTERS' REPORTING SERVICE

1 DETAILS; FOR EXAMPLE, THE DEVELOPMENT PLAN AND
2 LOGISTICS HAVE MAJOR FLAWS. THERE IS ALSO A LACK OF
3 PRELIMINARY EFFICACY DATA."

4 THE FOLLOWING SET OF BULLET POINTS EXPOUND
5 UPON THAT CENTRAL TENET. AS YOU GO DOWN FURTHER,
6 THERE'S ADDITIONAL COMMENTS WHICH AREN'T NECESSARILY
7 CRITIQUES OR STRENGTHS. THEY'RE JUST SUGGESTIONS
8 THAT THE REVIEW PANEL HAS MADE TO THE TEAM, AND IT
9 PROPOSED IDEAS THAT IT PERHAPS COULD BE A GOOD IDEA
10 FOR THE TEAM TO MOVE FORWARD WITH.

11 MR. SHEEHY: THANK YOU, DR. THAKAR. IS
12 THERE BOARD DISCUSSION?

13 DR. HIGGINS: IF I COULD JUST EXPOUND ON
14 MY REQUEST TO THE BOARD. THERE ARE TWO POINTS TO
15 MAKE IN FAVOR OF FUNDING THIS AT THIS TIME THAT HAVE
16 TO DO WITH ADDITIONAL DATA THAT WERE -- THE
17 APPLICATION WAS DUE IN NOVEMBER OF 2015 AND WAS
18 REVIEWED IN FEBRUARY, AND THERE WAS DATA GENERATED
19 IN THE INTERIM THAT'S RELEVANT TO SOME OF THE
20 CRITICISMS OF THE GWG. I WANT TO BE REALLY CLEAR
21 THAT I'M NOT TAKING AN ISSUE WITH THE GWG'S REVIEW
22 OR ANY OF THEIR FINDINGS. IT'S JUST THE PRESENCE OF
23 NEW DATA.

24 AND THE SECOND POINT TO MAKE, ACTUALLY
25 STEVE BROUGHT IT UP EARLIER, THE WHOLE ISSUE OF

BARRISTERS' REPORTING SERVICE

1 PROGRAMMATIC REVIEW. THERE IS NOT A FORMAL REVIEW,
2 BUT CERTAINLY THE BOARD HAS AT ITS DISCRETION
3 PROGRAMMATIC CONSIDERATIONS IN AREAS THAT WE MAY BE
4 LACKING, AND CERTAINLY PARKINSON'S DISEASE IS ONE OF
5 THOSE, A VERY IMPORTANT ONE THAT I THINK WE THOUGHT
6 EARLY ON BACK IN 2004 WAS GOING TO BE SORT OF THE
7 LOW HANGING FRUIT AND EASY TO SOLVE BECAUSE WE
8 UNDERSTOOD THEM LIKE THEY'RE BASIS OF THE DISEASE,
9 AND THAT HAS NOT COME TO BE THE CASE.

10 THOSE ARE MY TWO POINTS IN FAVOR OF
11 CONSIDERATION OF FUNDING. WHAT I WOULD ADD TO THAT
12 IS THAT THIS MAY BE UNORTHODOX, BUT TO TAKE A
13 CREATIVE APPROACH TO DOING THIS. AND GIVEN THE
14 DEFICIENCIES THAT WERE JUST OUTLINED, PERHAPS WE
15 COULD CONSIDER FUNDING THIS WITH CONTINGENCIES. THE
16 CONTINGENCIES MIGHT BE FOR THE APPLICANT AND CIRM
17 STAFF TO GET TOGETHER AND IDENTIFY THE MILESTONES
18 THAT WOULD BE NECESSARY IN ORDER FOR THIS RESEARCH
19 TO BE TRANSLATIONAL MATERIAL READY. IN EXCHANGE FOR
20 THAT, PERHAPS THE APPLICANT COULD FUND THAT RESEARCH
21 THEMSELVES OR FIND FUNDING FOR THAT RESEARCH. AND
22 WHAT WE WOULD PROVIDE IN EXCHANGE, UPON COMPLETION
23 OF THOSE MILESTONES, WITHOUT FURTHER ADJUDICATION,
24 IS ENTERING THEM INTO THE TRANSLATION PROGRAM. SO
25 NOT MAKE THEM GO BACK THROUGH THE HURDLE OF APPLYING

BARRISTERS' REPORTING SERVICE

1 FOR A TRANSLATIONAL GRANT AGAIN, BUT HOLDING THEM TO
2 MEETING CERTAIN MILESTONES AS A CONTINGENCY FOR
3 FUNDING. IF THAT'S CONFUSING, I'LL TRY TO SIMPLIFY
4 IT.

5 MR. PANETTA: THANK YOU, MR. SHEEHY. SO I
6 WANT TO EXPAND ON MY REASON FOR SECONDING THE
7 MOTION, AND IT GOES BACK TO WHAT DAVID SAID IN THE
8 BEGINNING OF HIS COMMENTS. WE'VE BEEN AT THIS FOR
9 12 YEARS, AND THIS WAS INITIALLY EXPECTED TO BE LOW
10 HANGING FRUIT. NOT MUCH HAS COME FORWARD IN THE WAY
11 OF OPPORTUNITY TO DEVELOP STEM CELL THERAPIES TO
12 TREAT PARKINSON'S PATIENTS OVER THE COURSE OF THE 12
13 YEARS THAT WE'VE BEEN AT THIS. AND SO I SEE THIS AS
14 AN OPPORTUNITY, AND I SEE IT ALSO AS A SUCCESSFUL
15 WAY FORWARD GIVEN WHAT DAVID IS PROPOSING, THAT WE
16 GO BACK TO THE GRANTS WORKING GROUP OR THE APPLICANT
17 GO BACK TO THE GRANTS WORKING GROUP TO CORRECT THESE
18 DEFICIENCIES OR TO EXPLAIN THE CORRECTIONS FOR THE
19 DEFICIENCIES BECAUSE I THINK, ALSO, THAT IT SHOULD
20 BE UP TO THE ICOC TO TAKE AT FACE VALUE WHAT IS
21 CONTAINED IN THE COMMENTS THAT WE RECEIVED FROM DR.
22 LORING.

23 IF, TO THE SATISFACTION OF THE GWG, THESE
24 CONCERNS HAVE BEEN ADDRESSED, THEN WE CAN MOVE
25 FORWARD WITH HOPEFULLY A PATH TOWARD DEVELOPING A

BARRISTERS' REPORTING SERVICE

1 THERAPY FOR PARKINSON'S. THIS IS OUR ONE
2 OPPORTUNITY, AT LEAST IN THE TIME THAT I'VE BEEN
3 HERE, THAT I'VE SEEN, AND I DON'T KNOW THAT THERE'S
4 BEEN ANYTHING BEFORE THAT.

5 MR. SHEEHY: ARE THERE OTHER? MR.
6 JUELSGAARD.

7 MR. JUELSGAARD: YES, I HAVE A COUPLE
8 QUESTIONS FOR DR. THAKAR. SO AS I UNDERSTAND IT,
9 THESE APPLICATIONS WERE SUBMITTED IN LATE NOVEMBER
10 AND ADJUDICATED BY THE GWG IN FEBRUARY. IS THAT
11 CORRECT?

12 DR. THAKAR: THAT IS CORRECT, SIR. THEY
13 ARRIVED, I BELIEVE, I DON'T REMEMBER OF THE DAY OF
14 THE WEEK, BUT IT WAS NOVEMBER 20, 2015. AND THE
15 REVIEW WAS FEBRUARY 11TH AND 12TH OF 2016.

16 MR. JUELSGAARD: IS THERE ANOTHER
17 SUBMISSION DATE FOR THESE TRANSLATIONAL PROJECTS AND
18 ANOTHER REVIEW DATE THAT'S ALREADY BEEN ESTABLISHED?

19 DR. THAKAR: YES, SIR. IT'S JULY 15TH,
20 2016, IS THE NEXT TRAN1, 2, 3, 4 APPLICATION
21 DEADLINE. THE REVIEW WILL OCCUR EARLY OCTOBER.

22 MR. JUELSGAARD: ALL RIGHT. SO WE HANDLE
23 THESE IN A SLOWER FASHION THAN WE DO THE CLINICAL
24 ONES?

25 DR. THAKAR: TWICE A YEAR.

BARRISTERS' REPORTING SERVICE

1 MR. JUELSGAARD: GOT IT. SO THE SECOND
2 QUESTION IS, AND, DR. MILLS, CLARIFIED DURING HIS
3 PRESIDENT'S REPORT THAT NOW IF YOU FALL INTO TIER
4 III IN THE CLINICAL AREA, YOU STILL GET A SECOND
5 BITE OF THE APPLE AS LONG AS YOU CAN DO IT WITHIN
6 SIX MONTHS. HERE THE SCORING IS 85 GO, LESS THAN 85
7 NO GO. ON THE LESS THAN 85 NO GO, IS THERE A CHANCE
8 TO COME BACK AND REDO YOUR TRANSLATIONAL APPLICATION
9 AND HAVE IT RESUBMITTED TO THE GWG FOR
10 CONSIDERATION?

11 DR. MILLS: SO I JUST WANT TO CLARIFY,
12 FIRST OF ALL, WHAT WE'RE PROPOSING FOR NEXT MONTH IS
13 A CHANGE IN THE 3. AND THAT CHANGE IN THE 3 DOESN'T
14 SAY COME BACK IF YOU CAN WITHIN SIX MONTHS. IT SAYS
15 YOU CAN'T COME BACK FOR AT LEAST SIX MONTHS. SO
16 IT'S A SIX MONTHS FORCED OUT DEFERRAL.

17 WITH REGARDS TO THIS, I THINK HISTORICALLY
18 WE DIDN'T DO THESE PREDICTABLY. SO UNDER THE 1.0
19 SYSTEM, AS WE WOULD SIT HERE TODAY AND WE WERE
20 REVIEWING AND MAKING DECISION ON A TRAN1 AWARD, WE
21 COULDN'T TELL YOU WHEN THE NEXT TRAN1 PROGRAM WAS
22 GOING TO BE RUN. SOMETIMES IT MIGHT BE NINE MONTHS,
23 SOMETIMES IT MIGHT BE IN 18 MONTHS. WE DIDN'T HAVE
24 A SET SCHEDULE. SO WE WENT TO THE 2.0 VERSION OF
25 THAT TO SAY WE'RE GOING HAVE THESE THINGS GO OFF AS

BARRISTERS' REPORTING SERVICE

1 RAPIDLY AS WE PRACTICALLY CAN. AND GIVEN WE'RE
2 DOING THE 12 CLINICAL REVIEWS, WE DO TWO TRANS
3 REVIEWS AND TWO DISCOVERY REVIEWS EVERY YEAR. SO
4 THESE REVIEWS ARE GOING OFF EVERY SIX MONTHS.

5 BECAUSE THEY GET THE FEEDBACK IN TIME TO
6 INFLUENCE THE NEXT APPLICATION, THE THINKING IS
7 THAT, SINCE THE NEXT APPLICATION PROCESS COMES UP SO
8 QUICKLY, YOU CAN MAKE MATERIAL CHANGES AND
9 IMPROVEMENTS TO YOUR APPLICATION, THAT THAT'S
10 BASICALLY THE REMEDY TO IT IS TO TAKE THE COMMENTS
11 AND REAPPLY.

12 MR. JUELSGAARD: THANK YOU. THAT'S WHAT I
13 ASSUMED.

14 SO, IN ESSENCE, WHAT WE'RE DISCUSSING HERE
15 IS -- LET'S ASSUME FOR A MOMENT THAT DR. LORING'S
16 LETTER ADDRESSES ALL OF THE ISSUES THAT WAS
17 CONCERNING THE GWG. I DON'T KNOW WHETHER THEY DO OR
18 NOT. I'M NOT A GWG MEMBER. IN ESSENCE, YOU'D HAVE
19 TO TAKE HER AT HER WORD THAT, IN ESSENCE, THEY HAVE,
20 WHICH I THINK IS A DIFFICULT PROPOSITION, AT LEAST
21 FOR ME. AND WITH ALL DUE RESPECT TO HER, I THINK
22 SHE'S A GREAT SCIENTIST, BUT THE GWG REVIEW IS NOT A
23 REVIEW THAT WE DO HERE.

24 SO REALLY WHAT WE'RE TALKING ABOUT IS,
25 ASSUMING THAT SHE'S CORRECT AND SHE ESSENTIALLY OR

BARRISTERS' REPORTING SERVICE

1 THEY HAVE ADDRESSED ALL THESE ISSUES, WE'RE TALKING
2 ABOUT A DELAY OF SIX MONTHS IN A TRANSLATIONAL
3 PROGRAM. IN OTHER WORDS, MY ASSUMPTION IS THAT NEXT
4 TIME THEY'LL GET A SCORE ABOVE 85 IF THEY WERE TO
5 REAPPLY AND EVERYTHING WOULD BE A GO AT THAT POINT.

6 IS THAT A FAIR ASSESSMENT OF PROBABILITY
7 OR POSSIBILITY HERE?

8 DR. MILLS: THAT'S THE WAY THE SYSTEM IS
9 SET UP. SO WE GET YOUR FEEDBACK BACK BEFORE THE
10 NEXT SIX-MONTH REVIEW CYCLE STARTS.

11 MR. JUELSGAARD: SO THE TRADE-OFF IS SIX
12 MONTHS VERSUS OUR WILLINGNESS TO ACCEPT THAT TEAM'S
13 BELIEF THAT THEY'VE ADDRESSED THE GWG'S CONCERNS.
14 I'M SORRY. THAT'S NOT A QUESTION FOR YOU. THAT'S
15 JUST A STATEMENT FROM ME.

16 DR. DULIEGE: SO MY COMMENT HERE IS THAT
17 THERE'S NOTHING MORE THAT WE'D LIKE TO SEE APPROVED
18 THAN SUCH PROPOSAL AND MOVING RESEARCH IN
19 PARKINSON'S DISEASE FOR THE REASON THAT BOTH YOU,
20 DR. PANETTA AND DAVID, SO ELOQUENTLY OUTLINED. AND
21 FOR FULL DISCLOSURE, I'M SORT OF AN ADVOCATE HERE
22 BECAUSE MY FAMILY HAS SUFFERED FROM PARKINSON'S
23 DISEASE, INCLUDING MY FATHER WHO PASSED AWAY. SO I
24 HAVE ALL REASONS TO APPROVE. AND I KNOW THAT FOR
25 PATIENTS AND PATIENT ADVOCATES SIX MONTHS OF SUCH A

BARRISTERS' REPORTING SERVICE

1 DIFFICULT RESEARCH IS AN EXTREMELY LONG TIME.

2 THAT BEING SAID, AND I READ DR. LORING'S
3 RESEARCH, WE'VE SEEN HER, SHE'S COME HERE THE FIRST
4 TIME, SHE'S A WELL-KNOWN SCIENTIST HERE, BUT I'M A
5 LITTLE SURPRISED THAT EVERYTHING WOULD BE ADDRESSED
6 BY A PUBLICATION. I DON'T BELIEVE THAT WHAT WE SAW
7 AS THE COMMENT, THE ANSWER WAS, WELL, IN THE
8 MEANTIME THINGS WERE PUBLISHED. MAYBE YOU CAN HELP
9 US BETTER UNDERSTAND THAT.

10 THE CHALLENGE THAT I SEE IS THAT THE
11 AVERAGE SCORE HERE WAS 70. THAT'S A VERY BAD SCORE.
12 WE'RE NOT TALKING ABOUT AN 83 SCORE AND TRYING MOVE
13 THINGS FROM BORDERLINE TO ABOVE THE BORDERLINE. AND
14 THERE WAS NO SCORE ABOVE 80. SO I JUST WOULD LIKE
15 TO HAVE YOUR PERSPECTIVE ON THAT.

16 MR. PANETTA: AND I COMPLETELY UNDERSTAND,
17 AND I TOO APPROACH IT FROM THE STANDPOINT OF BEING
18 AN ADVOCATE BECAUSE OF THE FACT THAT PARKINSON'S
19 AFFECTS MY FAMILY TOO.

20 THIS IS AN EXCEPTIONAL CASE. AND I THINK
21 WE HAVE TO ALSO APPRECIATE THE FACT THAT PARKINSON'S
22 AFFECTS SUCH A LARGE PORTION OF THE POPULATION. AND
23 I AGREE THAT THIS IS A LOW SCORE. AND I ALSO AGREE
24 WITH MR. JUELSGAARD, THAT IT'S NOT UP TO US TO
25 DECIDE WHETHER DR. LORING HAS ADDRESSED THESE

BARRISTERS' REPORTING SERVICE

1 QUESTIONS ADEQUATELY. IT'S UP TO THE GWG.

2 BUT MY CONCERN DOES GO TO THE EXPEDITIOUS
3 NEED HERE THAT WE HAVE TO ADDRESS PARKINSON'S AND
4 THE FACT THAT WE HAVEN'T REALLY BEEN ABLE TO DO MUCH
5 TO ADDRESS IT FOR THE TIME THAT THIS INSTITUTION HAS
6 EXISTED.

7 SO IF I UNDERSTAND WHAT DAVID IS
8 PROPOSING, IT IS THAT WE EXPEDITE THE RETURN OF THIS
9 APPLICATION TO THE GWG SO THAT IT CAN BE CONSIDERED
10 IN A MUCH LESSER TIME FRAME THAN TO WAIT FOR SIX
11 MONTHS TO BE ABLE TO DO THAT. THAT'S REALLY WHERE I
12 WOULD BE GOING WITH THIS.

13 DR. DULIEGE: THANK YOU, DR. PANETTA.
14 THAT'S A GREAT CLARIFICATION, BUT IS THERE SUCH A
15 PROCESS FOR THAT?

16 DR. MILLS: IS THERE CURRENTLY A PROCESS
17 FOR THAT? NO, BUT WE WORK AT THE WILL OF THE BOARD.

18 DR. DULIEGE: SO IF THAT'S A NEW MOTION,
19 WOULD THAT BE SORT OF A REALISTIC PROPOSAL?

20 DR. MILLS: WE CAN RE-REVIEW THINGS.
21 THAT'S POSSIBLE.

22 MR. SHEEHY: CAN WE GET SOME CLARITY ON
23 THE MOTION BECAUSE I THINK THE MOTION WE HAVE BEFORE
24 US IS SIMPLY TO APPROVE -- TO MOVE THIS GRANT INTO
25 THE FUNDABLE CATEGORY. IF THERE'S A MORE NUANCED

BARRISTERS' REPORTING SERVICE

1 MOTION, PERHAPS THE MAKER AND THE SECOND COULD COME
2 TO --

3 DR. HIGGINS: I'LL PROPOSE AN AMENDED
4 MOTION OR RETRACT MY PREVIOUS ONE AND PROVIDE A NEW
5 ONE, HOWEVER YOU WANT TO DO IT. I WOULD PROPOSE
6 GRANT APPROVAL FOR THE TRANSLATION GRANT WITH
7 CONTINGENCIES. THOSE CONTINGENCIES INCLUDE THAT THE
8 APPLICANT WORK WITH CIRM STAFF OR VIA CIRM STAFF
9 THROUGH THE GWG TO AGREE UPON SPECIFIC ACTIVITIES OR
10 DATA THAT WOULD LEAD TO SPECIFIC MILESTONES THAT
11 WOULD SATISFY THE GWG CONCERNS THAT HAVE BEEN
12 OUTLINED IN THEIR REVIEW.

13 NEXT, THE APPLICANT WOULD THEMSELVES, WE'D
14 ASK THEM TO TAKE ON THE FUNDING OF COMPLETING THOSE
15 SPECIFIC ACTIVITIES THAT ARE NEEDED TO ADDRESS THE
16 GWG CONCERNS. ESSENTIALLY WHAT THAT DOES IS BRING
17 THEM UP TO THE POINT OF BEING QUALIFIED FOR ALL THE
18 TRANSLATIONAL ACTIVITIES THAT WOULD GO FORWARD.

19 AND THEN SUCCESSFUL COMPLETION OF THAT
20 WOULD RESULT IN AN IMMEDIATE AWARD OF THE
21 TRANSLATION GRANT AS OPPOSED TO HAVING THAT TO BE
22 ADJUDICATED BY THE GWG. SO IN OTHER WORDS, THEY
23 WOULD BE AWARDED THE GRANT BY THE BOARD WITH
24 CONTINGENCIES AS OPPOSED TO HAVING TO GO THROUGH THE
25 PROCESS IN JULY OR THEREAFTER FOR ANOTHER REVIEW.

BARRISTERS' REPORTING SERVICE

1 AND THE BENEFIT THERE, AS MR. PANETTA HAS POINTED
2 OUT, IS A TIME SAVINGS, HUGE TIME SAVINGS.

3 MR. SHEEHY: LET ME JUST DO -- I HAVE
4 DR. DULIEGE AND MR. JUELSGAARD, BUT I JUST WANT TO
5 GET THE MOTION, SOME CLARITY ON THE MOTION. IS THIS
6 MOTION THAT DAVID IS PROPOSING ACCEPTABLE TO YOU?

7 MR. PANETTA: IF THAT'S A MOTION, I WOULD
8 SECOND THAT MOTION.

9 DR. HIGGINS: THAT'S A MOVEMENT, NOT A
10 MOTION.

11 MR. SHEEHY: SO YOU HAVE DECISION POINTS.
12 SO THE IDEA IS THAT THE CIRM TEAM WOULD BE
13 RESPONSIBLE FOR MAKING THOSE DECISIONS?

14 DR. HIGGINS: MY PROPOSAL WOULD BE THAT
15 THE APPLICANT WORK WITH THE CIRM TEAM TO GENERATE
16 MUTUALLY AGREED UPON MILESTONES TO ACHIEVE THE GWG
17 CONCERNS.

18 MR. SHEEHY: RIGHT. BUT MUTUALLY AGREED,
19 I THINK -- AM I THE ONLY ONE THAT FEELS LIKE --
20 JAMES, PERHAPS YOU HAVE A THOUGHT.

21 MR. HARRISON: JUST TO ASK A QUESTION SO I
22 MAKE SURE THAT THE CIRM TEAM UNDERSTANDS THE MOTION.
23 ONCE THE MILESTONES ARE NEGOTIATED AND THE
24 ACTIVITIES ARE COMPLETED, WOULD CIRM BE CHARGED WITH
25 THE AUTHORITY TO MAKE THE DECISION AS TO WHETHER OR

BARRISTERS' REPORTING SERVICE

1 NOT THE MILESTONES HAD BEEN SATISFIED?

2 DR. HIGGINS: THAT'S MY PROPOSAL.

3 MR. HARRISON: THANK YOU.

4 MR. SHEEHY: OKAY. SO I HAVE A WHOLE
5 LIST, SO DR. DULIEGE, THEN MR. JUELSGAARD. I HOPE
6 I'M GETTING YOU IN THE RIGHT ORDER. AND THEN DR.
7 LUBIN. CAN WE PERHAPS PROCEED?

8 DR. DULIEGE: SO, DAVID, I REALLY
9 APPRECIATE, FRANKLY, THE CREATIVITY TO TRY TO FIND A
10 WAY TO MOVE THINGS FORWARD. IN GENERAL, I THINK OUR
11 RESPONSIBILITY IS NOT JUST TO ABIDE BY THE RULES,
12 BUT IN SOME SITUATIONS, SPECIFIC SITUATIONS, TO TRY
13 TO FIND A CREATIVE WAY OF MOVING FORWARD. I WOULD
14 BE MORE IN FAVOR OF WHAT WAS PRESENTED EARLIER,
15 WHICH WAS TO ASK RANDY AND THE CIRM TO WORK ON AN
16 ACCELERATED PATHWAY FOR RE-REVIEW BECAUSE IN BENDING
17 THE RULE, THAT'S CLEAR. WHAT YOU'RE ASKING IS A NEW
18 PROCESS WHERE THERE'S A NEW DECISION TO BE MADE BY
19 THE CIRM ON THIS ONE.

20 BEFORE I WOULD SUGGEST THAT WE EVEN VOTE
21 ON THAT, WE SHOULD HEAR FROM RANDY. IF THAT WERE TO
22 BE THE VOTE, WOULD YOU BE IN FAVOR OF THAT AND WOULD
23 IT BE POSSIBLE TO APPLY IT?

24 DR. MILLS: SO I WANT TO BE REALLY CLEAR
25 ON THIS. WE ARE NOT IN FAVOR OR WE ARE NOT AN

BARRISTERS' REPORTING SERVICE

1 AGAINST AGENCY IN TERMS OF APPLICATIONS. WE HAVE A
2 PROCESS, AND IT'S A RECURRING PROCESS. AND WHAT WE
3 ATTEMPT TO DO IS RUN IT AS FAIRLY AND AS EQUITABLY
4 AS WE CAN FOR ALL PARTIES.

5 WE'VE REVIEWED THE PROCESS, AND WE BELIEVE
6 IN THIS CASE THIS PROCESS WAS RUN FAIRLY AND
7 EQUITABLY, AND THERE WAS THOROUGH DISCUSSION. AND
8 THAT'S WHY WE PUT IN THOSE VERY SPECIFIC VOTES AT
9 THE END SO THAT WE HAVE THESE TIMES WE CAN SAY THAT
10 THE PROCESS RAN. THAT'S WHAT WE DO THOUGH IS WE RUN
11 PROCESS. OBVIOUSLY THE BOARD, AND DR. THOMAS AND
12 THE REST CAN OPINE ON THIS BETTER THAN I, MAKE
13 DECISIONS OUTSIDE OF THE PROCESS FROM TIME TO TIME.
14 SO WE DIDN'T SEE WHERE THE PROCESS BROKE DOWN.

15 IF YOU WERE TO INSTRUCT US TO DO SOMETHING
16 DIFFERENTLY, THEN WE WILL, OF COURSE, DO THAT.

17 MR. SHEEHY: MR. JUELSGAARD AND THEN I'LL
18 HAVE DR. LUBIN AND THEN DR. LAPORTE.

19 MR. JUELSGAARD: SO THIS IS JUST TO SEEK A
20 LITTLE CLARITY FOR MYSELF. SO GOING BACK A LITTLE
21 WAYS IN TIME, WE USED TO HAVE A PROCESS, AND WE MAY
22 STILL HAVE IT, I'M NOT SURE, SO WE WOULD HAVE THREE
23 TIERS. AND THAT WAS FOR EVERY SORT OF APPLICATION
24 THAT WE CONSIDERED, INCLUDING TRANSLATIONAL
25 APPLICATIONS. AND SOMETIMES THINGS WOULD WIND UP IN

BARRISTERS' REPORTING SERVICE

1 TIER II, BUT THE APPLICANT WOULD COME FORWARD WITH A
2 LETTER SAYING, AH, BUT WE HAVE NEW INFORMATION, NEW
3 SCIENTIFIC INFORMATION, AND WE THINK THAT MIGHT HAVE
4 MADE A DIFFERENCE IN TERMS OF THE OUTCOME OF THE GWG
5 VOTE.

6 AND SO THE CIRM, AS I REMEMBER, I'M SURE
7 PEOPLE WILL CORRECT ME WHERE I'M WRONG, AND I HOPE
8 THEY DO, BUT THE CIRM STAFF WOULD REVIEW THIS NEW
9 SCIENTIFIC INFORMATION, DETERMINE INDEED WHETHER OR
10 NOT IT WAS NEW SCIENTIFIC INFORMATION AND, IF IT
11 WAS, SUBMIT IT TO A TEAM OF THREE GWG MEMBERS, THE
12 CHAIRMAN OF THAT PARTICULAR GWG REVIEW GROUP AND TWO
13 ADDITIONAL MEMBERS OF THAT GROUP, FOR
14 RECONSIDERATION, SO AT A VERY ABBREVIATED AND
15 SCALED-DOWN PROCESS. AND EITHER THEN IT MOVED UP
16 INTO TIER I OR IT STAYED WHERE IT WAS.

17 DO WE STILL HAVE ANY -- AND SO MY FIRST
18 QUESTION IS DOES ANYBODY REMEMBER IT DIFFERENTLY
19 WITHIN THE GROUP?

20 DR. MILLS: YOU'RE REFERRING TO OUR
21 PREVIOUS APPEAL POLICY. AND I'LL FIRST SAY THAT
22 THAT POLICY EXISTED BECAUSE YOU DIDN'T KNOW WHEN THE
23 NEXT TRAIN WAS EVER GOING TO RUN. SO APPEALING WAS
24 A MORE CRITICAL EVENT AT THAT TIME. BUT, JAMES, IS
25 THAT EXACTLY THE --

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN THOMAS: SO LET ME JUST GIVE A
2 LITTLE CLARITY AND ADD TO WHAT MR. JUELSGAARD IS
3 SAYING. A COUPLE OF MEMBERS OF THE BOARD HAVE ASKED
4 ME THIS, JUST TO SORT OF TRACE THE HISTORY OF THE
5 APPELLATE PROCESS SO EVERYBODY UNDERSTANDS.

6 IF YOU GO BACK TO AS RECENTLY AS 2012, WE
7 HAD NO REAL APPELLATE PROCESS. AND ANYBODY WHO WAS
8 NOT RECOMMENDED FOR FUNDING COULD COME TO THE BOARD
9 AND PRESENT AN APPEAL, AND THE BOARD AT THAT POINT,
10 SINCE THERE REALLY WAS NO APPELLATE PROCESS, COULD
11 EITHER MAKE A DECISION TO FUND OR NOT, BUT IT WAS
12 BASICALLY RESPONDING TO THE SPEAKER AND TO WHAT WAS
13 PRESENTED IN THE APPEAL ITSELF.

14 THAT WAS, I THINK, A PROBLEMATIC PROCEDURE
15 BECAUSE IT WAS VERY DIFFICULT FOR THE BOARD SITTING
16 AS IT DID TO DECIDE WHETHER OR NOT WHAT THEY WERE
17 HEARING AS WHETHER IT WAS NEW INFORMATION OR
18 CORRECTION OF DISPUTES OF MATERIAL FACTS OR WHETHER,
19 IN FACT, THAT WAS INDEED THE CASE OUTSIDE THE
20 CONTEXT OF A GWG REVIEW.

21 SHORTLY AFTER THAT WE GOT THE IOM REPORT,
22 AND PART AND PARCEL OF OUR RESPONSE TO THE IOM
23 REPORT WAS TO INITIATE AN APPELLATE PROCESS, WHICH
24 DR. JUELSGAARD IS REMEMBERING CORRECTLY, WHICH WAS,
25 INSTEAD OF THE BOARD DECIDING ON THE SPOT, IT WOULD

BARRISTERS' REPORTING SERVICE

1 BE REFERRED -- ANY APPEAL WOULD BE AUTOMATICALLY
2 REFERRED TO THE CIRM TEAM FOR ITS REVIEW BASED ON
3 WHAT WAS SUBMITTED. AND IF IT FELT THAT IT WAS A
4 COMPELLING CASE, THE NEXT STEP WAS TO CONVENE A
5 SUBGROUP OF THE GWG TO HEAR THE RECONSIDERATION
6 BASED ON THE DATA THAT WAS PRESENTED. IF THAT, IN
7 FACT, OR EVEN IF IT DIDN'T, LED TO AN APPROVAL GOING
8 FORWARD, THAT WAS THEN SUBJECT TO RECOMMENDATION
9 AGAIN BY THE TEAM TO THE BOARD, AND THE BOARD AT
10 THAT POINT WOULD HAVE A DISCUSSION UNDER THE CONTEXT
11 OF PROGRAMMATIC REVIEW.

12 THAT WHOLE APPELLATE PROCESS WAS
13 EFFECTIVELY NEGATED, OR I SHOULD SAY NOT NEGATED.
14 THERE REALLY WAS NO NEED TO CONTINUE THAT ONCE CIRM
15 2.0 HAD BEEN PUT IN PLACE AND A REGULARIZED SYSTEM
16 OF APPLICATION AND REVIEW WAS INSTITUTED SUCH THAT
17 IF SOMEBODY WAS NOT RECOMMENDED FOR FUNDING, THEY
18 COULD RESUBMIT UNDER THE INTERVAL THAT CORRESPONDED
19 TO THE LEVEL OF APPLICATION IN QUESTION. AND AT
20 THAT POINT YOU WOULD UNDERGO RE-REVIEW, EFFECTIVELY
21 RE-REVIEW, BY THE ENTIRE GWG, AND IT WOULD WORK
22 THROUGH THE PROCESS AND COME BACK TO THE BOARD BASED
23 ON THAT.

24 SO THAT, MR. JUELSGAARD, IS WHAT WE HAVE
25 IN PLACE. AND FOR NEWER MEMBERS OF THE BOARD,

BARRISTERS' REPORTING SERVICE

1 THAT'S HOW WE GOT WHERE WE ARE. HOPE THAT ANSWERS
2 THAT QUESTION.

3 MR. SHEEHY: THEN I HAD DR. LUBIN AND THEN
4 DR. LAPORTE.

5 DR. LUBIN: SO MY CONCERN IS THIS IS NOT
6 AN UNCOMMON EVENT. IS THIS WHAT WE WANT TO DO ON
7 ALL APPLICATIONS THAT ARE AT THIS MIDSCORE LEVEL OR
8 NEW DATA IS OBTAINED FROM THE TIME THE APPLICATION
9 WAS REVIEWED FOR AN INDEPENDENT REVIEW OR
10 PROCESSING? THERE WILL BE A NUMBER OF APPLICATIONS
11 THAT FIT INTO IT.

12 I THINK THE AREA OF RESEARCH IS OBVIOUSLY
13 IMPORTANT. PARKINSON'S DISEASE IS A MAJOR
14 CHALLENGE. ARE WE GOING TO HAVE ADVOCATES FOR EACH
15 DISEASE IF IT GETS IN THE 50 OR 70 RANGE WHERE
16 THERE'S NEW DATA TO HAVE ANOTHER REVIEW, OR ARE WE
17 GOING TO GO ALONG WITH WHAT RECOMMENDATIONS ARE
18 MADE? I THINK THAT'S WHAT WE'RE VOTING ON IN MY
19 OPINION.

20 MR. SHEEHY: DR. LAPORTE.

21 MS. LAPORTE: I GUESS I WOULD BASICALLY
22 JUST SECOND WHAT WAS JUST SAID. I WANTED TO JUST
23 KIND OF MAKE A STATEMENT ABOUT THE IMPORTANCE OF
24 PROCESS EVEN THOUGH I'M VERY SYMPATHETIC TO THE
25 CAUSE HERE. IT JUST FEELS LIKE SUCH A SLIPPERY

BARRISTERS' REPORTING SERVICE

1 SLOPE. JUST IN THIS GROUP WE HAVE, I THINK, SIX
2 OTHER APPLICATIONS THAT SCORED HIGHER THAT DON'T
3 TODAY HAVE A PROPOSAL TO DO SOMETHING OTHER THAN THE
4 PROCESS.

5 AND A CONTINGENT APPROVAL ALSO FEELS LIKE
6 IT PUTS A HUGE BURDEN ON OUR STAFF. I GUESS WITH
7 RESPECT FOR THE COMMUNITY OF PATIENTS HERE, IT JUST
8 FEELS LIKE PERSONALLY LIKE WE SHOULD STICK WITH THE
9 PROCESS.

10 DR. DULIEGE: YOU KNOW, KATHY, WITH
11 ENORMOUS RESPECT TO THE STAFF, I THINK WORK FROM THE
12 STAFF IS REALLY IMPORTANT, BUT HERE THESE ARE
13 PATIENT'S FUTURE OF DISEASE. SO I'M SURE THEY WILL
14 BE MORE THAN HAPPY TO WORK MORE TO MAKE THINGS
15 HAPPEN FASTER.

16 BUT MY QUESTION, RANDY, TO YOU IS I THINK
17 YOU AND THE CIRM TEAM ARE THE VICTIM OF THEIR OWN
18 SUCCESS, WHICH IS NOW YOU'VE SPOILED US. AND YOU
19 HAVE ACTUALLY SHOWED US THAT FROM THE CLINICAL PART,
20 YOU CAN GET TO THE NEXT REVIEW PROCESS PRETTY MUCH
21 EVERY MONTH, AS WE HEARD THIS MORNING. IS THERE A
22 WAY, AND I'M ASKING VERY HONESTLY, IS THERE A WAY TO
23 HAVE THE SAME REVIEW PROCESS FOR TRANSLATIONAL?

24 DR. MILLS: THE CLINICAL REVIEW GROUP IS A
25 LITTLE BIT EASIER TO HOLD TOGETHER BECAUSE IT'S

BARRISTERS' REPORTING SERVICE

1 BASICALLY A SIMILAR DISCIPLINE. AS YOU GO DOWN INTO
2 EARLIER AND EARLIER STAGE RESEARCH, SORT OF THE
3 BREADTH OF EXPERTISE YOU NEED BECOMES LARGER AND
4 LARGER, AND THE ENORMITY OF THE APPLICATIONS WE SEE
5 IS GREATER AND GREATER. AT ANY GIVEN REVIEW, WE
6 WILL SEE ONE OR TWO CLINICAL APPLICATIONS, BUT I
7 THINK HERE WE DID SOMETHING LIKE 40. AND SO IT'S A
8 COMBINATION OF THE BREADTH OF REVIEWERS WE NEED PLUS
9 THE VOLUME THAT WE GET IN THE EARLIER STAGE PROGRAMS
10 VERSUS THE CLINICAL STAGE PROGRAMS.

11 DR. DULIEGE: JUST TO FINISH ON THAT
12 BECAUSE WE NEED PROBABLY TO MOVE ON AND VOTE. JUST
13 TO EXPRESS MY OPINION, I WOULD VOTE IN FAVOR OF A
14 MOTION THAT ALLOWS TO FIND FOR THIS ONE AN
15 ACCELERATED PROCESS FOR ALL THE REASONS THAT WE
16 MENTIONED EARLIER, A MONTH OR SO, BUT GOING THROUGH
17 THE SAME PROCESS. I WOULD BE LESS ENTICED TO VOTE
18 IN FAVOR OF A MODIFIED PROCESS ALONG THE LINES OF
19 WHAT YOU SUGGESTED.

20 MR. PANETTA: THANK YOU. I WOULD SUPPORT
21 WHAT YOU JUST SAID, DR. DULIEGE. IN SECONDING THIS
22 MOTION, I DIDN'T INTEND FOR THIS TO BE A NEW
23 PROCESS. I INTENDED FOR THIS TO BE AN OPPORTUNITY
24 TO MAKE AN EXCEPTION THAT COULD GET THE CIRM STAFF
25 INVOLVED IN HELPING TO MAKE A DETERMINATION ON THIS

BARRISTERS' REPORTING SERVICE

1 AND NOT THAT WE CREATE A NEW PROCESS. AND, AGAIN,
2 THE EXCEPTION BEING THE FACT THAT THIS IS A VERY
3 SIGNIFICANT DISEASE THAT WE HAVEN'T COME UP WITH
4 ANYTHING ON IN THE YEARS THAT WE'VE BEEN HERE.

5 MR. SHEEHY: SO MAYBE I CAN ASK THE MAKERS
6 OF THE MOTION IF THERE'S A DESIRE TO CHANGE THEIR
7 MOTION TO ACCOMMODATE DR. DULIEGE'S CONCERNS? MAYBE
8 A SUBSTITUTE MOTION.

9 DR. DULIEGE: SO PROVIDING THAT IT'S
10 REALISTIC, I WOULD MAKE THE MOTION THAT THIS GOES TO
11 AN ACCELERATED REVIEW PROCESS.

12 MR. SHEEHY: AND ARE YOU WITHDRAWING YOUR
13 MOTION, DR. HIGGINS?

14 DR. HIGGINS: YES. I'LL WITHDRAW.

15 MR. SHEEHY: AND THE SECOND WITHDRAWS. DO
16 WE HAVE A SECOND TO --

17 MR. TORRES: SECOND.

18 MR. SHEEHY: SECOND FROM SENATOR TORRES.
19 AND THEN A COMMENT FROM --

20 DR. MILLS: NO, REALLY JUST A QUESTION.
21 SINCE WE'RE GOING TO DO THE WORK, IF WE COULD JUST
22 UNDERSTAND BETTER WHAT THE EXPECTATION OF THIS IS.
23 ARE WE GOING TO -- WHAT ARE WE REVIEWING?

24 MR. SHEEHY: AS I UNDERSTAND IT, IT IS AN
25 ACCELERATED REVIEW OF THE NEW MATERIAL. IF I SAY

BARRISTERS' REPORTING SERVICE

1 SOMETHING THAT'S WRONG, PLEASE. BUT IT'S
2 ACCELERATED REVIEW OF NEW MATERIAL. IS THERE A
3 DESIRE TO PUT A TIME FRAME ON THAT? DO YOU NEED A
4 TIME FRAME FOR THAT?

5 DR. MILLS: I WANT TO KNOW IF WE'RE
6 REVIEWING THE MATERIAL THAT THEY'VE SUBMITTED TODAY,
7 OR ARE WE REVIEWING -- ARE WE GETTING A NEW
8 APPLICATION, A REVISED APPLICATION, IN FROM THEM AND
9 RE-REVIEWING THAT?

10 MR. SHEEHY: I'LL ASK PERHAPS DR. DULIEGE
11 OR DR. HIGGINS.

12 DR. DULIEGE: TO SIMPLIFY THE PROCESS, I
13 WOULD ASK THE REVIEWERS TO WHICH EXTENT THE NEW
14 MATERIAL MODIFIES THE ASSESSMENT THAT WE HAVE BEEN
15 GIVEN.

16 MR. SHEEHY: DID YOU GET THAT, RANDY? AND
17 THEN, JAMES, YOU HAVE A QUESTION.

18 MR. HARRISON: SO MY QUESTION IS WHETHER
19 YOU'RE ANTICIPATING A REVIEW BY THE FULL GRANTS
20 WORKING GROUP OR A SUBSET OF THE GRANTS WORKING
21 GROUP AS WE USED WHEN WE HAD THE FORMER APPEALS
22 POLICY?

23 DR. DULIEGE: DO WE NEED TO BE THAT
24 DETAILED? I WOULD SORT OF AT THAT LEVEL LEAVE IT TO
25 YOU, RANDY, AND TO THE CIRM TO SAY WHAT'S FAIR AND

BARRISTERS' REPORTING SERVICE

1 REALISTIC. MY PROPOSAL, JUST MAKING IT AGAIN TO SEE
2 IF THAT WORKS, IS THAT CIRM REEVALUATE THE NEW
3 MATERIAL FOR THIS GRANT TO SEE IF THAT ULTIMATELY,
4 WITH EITHER A SMALLER TEAM OR LARGER TEAM, MODIFIES
5 THE OUTCOME AND THE SCORING OF THIS, AND THAT IT
6 WOULD BE DONE UNDER AN ACCELERATED SCHEDULE. I
7 DON'T NEED TO BE MORE SPECIFIC -- YOU WOULD KNOW
8 BETTER -- BETWEEN ONE AND THREE MONTH, BUT IT'S
9 TOTALLY CIRM'S PREROGATIVE TO DECIDE ON THAT.

10 MR. JUELSGAARD: COULD I ASK A QUESTION?
11 SO, DR. DULIEGE, ARE YOU ANTICIPATING ANY GWG REVIEW
12 OF THE NEW INFORMATION?

13 DR. DULIEGE: ARE YOU SAYING IN GENERAL OR
14 FOR THIS ONE?

15 MR. JUELSGAARD: IT DOESN'T MATTER TO ME
16 WHETHER IT'S A GENERAL OR THIS ONE OR NOT. EITHER
17 THEY NEED TO BE INVOLVED OR NOT, AND WE NEED TO KNOW
18 THAT. I THINK THEY DO NEED TO BE INVOLVED. THAT'S
19 MY OPINION. I DON'T THINK WE CAN JUST LEAVE THIS TO
20 CIRM MANAGEMENT. I DON'T THINK IT'S FAIR TO THEM TO
21 LEAVE TO CIRM MANAGEMENT. WE DECIDED WE WERE GOING
22 TO USE THE GRANTS WORKING GROUP TO MAKE
23 RECOMMENDATIONS A LONG TIME AGO, AND I THINK WE
24 SHOULD FOLLOW THAT PROCESS. SO FOR ME IT'S ALL
25 ABOUT IF WE'RE GOING TO DO THIS, HOW MANY GWG

BARRISTERS' REPORTING SERVICE

1 MEMBERS DO WE INVOLVE, AND WHAT WAS THEIR
2 RELATIONSHIP TO THE PRIOR REVIEW?

3 DR. DULIEGE: HERE, I AGREE THAT IT SHOULD
4 GO THROUGH THE GWG FOR REASONS YOU MENTIONED. I'M
5 NOT FAMILIAR ENOUGH TO THE PROCESS TO MAKE ANY FORM
6 OF RECOMMENDATION AS TO IT WOULD BE A SMALLER TEAM
7 OR THE FULL TEAM. I LEAVE IT TO PEOPLE WHO ARE PART
8 OF THE GWG TO MAKE A RECOMMENDATION HERE.

9 MR. SHEEHY: I SEE DR. PRICE HAS A
10 QUESTION.

11 DR. PRICE: CAN A NON-APPLICATION REVIEW
12 COMMITTEE MEMBER ENTER THIS DISCUSSION?

13 MR. HARRISON: YES, YOU CAN TO THE
14 DISCUSSION, YOU MAY NOT MAKE A MOTION OR VOTE,
15 PROVIDED THAT YOU DON'T HAVE A CONFLICT. AND YOU DO
16 NOT, DR. PRICE.

17 DR. PRICE: IT STRIKES ME THAT THE
18 DISTINCTION BETWEEN AN ACCELERATED REVIEW IN THIS
19 CASE AND ENUNCIATING A NEW POLICY IS REALLY A
20 DISTINCTION WITHOUT A DIFFERENCE BECAUSE ONCE WE
21 ENTER INTO THE ACCELERATION BY EXCEPTION, WHAT
22 PREVENTS OR WHAT WILL ALLOW THE BOARD WHEN SOMEBODY
23 ELSE COMES AT OUR NEXT MEETING WITH A CLAIM THAT
24 THEIR INFORMATION, THEY HAVE NEW INFORMATION, AND
25 THEY WANT A REVIEW, WHAT BASIS WOULD WE HAVE TO SAY

BARRISTERS' REPORTING SERVICE

1 NO? IF WE DON'T HAVE A BASIS, THERE IS NO BASIS TO
2 SAY NO, THEN WE'RE BACK TO THE JUELSGAARD
3 DESCRIPTION OF THE POLICY WE HAD BEFORE CIRM 2.0 WAS
4 INTRODUCED.

5 DR. HIGGINS: IT'S AN EXCELLENT POINT, DR.
6 PRICE. OF COURSE, WE DON'T WANT TO SAY NO TO
7 ANYBODY, BUT WE DO HAVE TO. AND I WOULD SAY THAT WE
8 RELY IN THAT INSTANCE ON PROGRAMMATIC
9 CONSIDERATIONS. IF WE'VE GOT GRANTS BEFORE US THAT
10 FILL A GAP THAT WE VIEW AS BEING A SIGNIFICANT GAP,
11 THAT WE SHOULD ALWAYS CONSIDER IT. AND IF WE'VE GOT
12 AN APPLICATION IN FRONT OF US FOR CONSIDERATION THAT
13 WE'VE GOT A HEALTHY, ROBUST PROGRAM IN ALREADY, THAT
14 PROBABLY THAT MIGHT CAUSE US TO VOTE AGAINST IT.

15 DR. PRICE: I UNDERSTAND THAT. WHAT IS A
16 SIGNIFICANT GAP IS, IN ESSENCE, IN THE EYES OF THE
17 BEHOLDER. AND GENERALLY EVERY ONE OF THE ADVOCATES
18 OF ONE OF THESE RESEARCH PROJECTS BELIEVES THAT
19 THEY'RE FILLING A SIGNIFICANT GAP AND COULD USE THE
20 TERMS OF OUR MISSION AS AN UNMET MEDICAL NEED.
21 SO...

22 MR. SHEEHY: SO JUST TO TAKE A MOMENT AND
23 HAVE SOME CLARITY. I THINK THERE'S AN OUTSTANDING
24 POINT ON WHICH WE HAVE NOT PROVIDED DIRECTION IN
25 TERMS OF THE MOTION, WHICH IS WHO WILL ACTUALLY BE

BARRISTERS' REPORTING SERVICE

1 CONDUCTING A REVIEW. I DON'T THINK THAT -- I THINK
2 THE CIRM TEAM WOULD PROBABLY PREFER THAT WE ACTUALLY
3 SPECIFY WHETHER IT'S THE FULL GRANTS WORKING GROUP
4 OR A SMALL SUBSET OF THE GRANTS WORKING GROUP AND TO
5 WHAT DEGREE IT SHOULD INCLUDE MEMBERS OF THE
6 ORIGINAL GRANTS WORKING GROUP THAT REVIEWED THE
7 APPLICATION.

8 SO I THINK IN TERMS OF HAVING A MOTION
9 THAT IS FEASIBLE FOR THE CIRM TEAM, THOSE QUESTIONS
10 NEED TO BE ANSWERED.

11 AND THEN THERE'S ONE OTHER QUESTION THAT
12 SHOULD ALSO BE ANSWERED IS WHETHER THAT
13 RECOMMENDATION THEN EFFECTIVELY BECOMES FUNDED ONCE
14 THAT'S CONCLUDED OR IF IT COMES BACK TO THE
15 APPLICATION REVIEW SUBCOMMITTEE, WHICH IS MEETING
16 MONTHLY, TO TAKE UP THAT ISSUE AND COMPLETE THE
17 PROCESS. SO THOSE QUESTIONS. AND I THINK THE TEAM
18 WOULD BE GRATEFUL IF WE ANSWERED THOSE. THERE'S A
19 DECISION POINT FOR THE MAKERS OF THE MOTION.

20 CHAIRMAN THOMAS: SO TO THE EXTENT THAT WE
21 WOULD ENTERTAIN THIS, AND I DO WANT TO POINT OUT
22 THAT THIS IS, AND I UNDERSTAND, DAVID, THIS IS A
23 DEVIATION FROM THE PROCESS THAT THE TEAM HAS TAKEN A
24 LOT OF TIME TO PUT TOGETHER, BUT IF WE DO CONSIDER
25 THIS, I THINK THE ONLY WAY TO DO THIS FAIRLY IS FOR

BARRISTERS' REPORTING SERVICE

1 THE ENTIRE GWG AND THE SAME GROUP, BECAUSE THEY'RE
2 THE ONES HAVING TO EVALUATE WHETHER OR NOT THE
3 INFORMATION CHANGES THEIR VIEW OF THINGS, SO IT
4 WOULD HAVE TO BE THE FULL GWG. AND THAT WHATEVER
5 THEIR DECISION WOULD BE WOULD COME BACK TO -- I
6 THINK WE WANT TO BE VERY CAREFUL ABOUT CREATING
7 SITUATIONS WHERE THERE'S AN EVALUATION WITHOUT THE
8 BOARD HAVING THE LAST WORD, THAT THAT WOULD HAVE TO
9 COME BACK REGARDLESS OF WHAT THE RECOMMENDATION IS
10 FOR CONSIDERATION AT THE NEXT CONVENED MEETING OF
11 THE APPLICATION REVIEW SUBCOMMITTEE.

12 DR. MILLS: JUST A COMMENT ON THAT. WE
13 CAN HOLD A FULL GWG. WE WILL ALMOST ASSUREDLY NOT
14 BE ABLE TO GET THE EXACT SAME MEMBERS BACK. THAT
15 BECOMES LOGISTICALLY FORMIDABLE. WE CAN CONSERVE AS
16 MANY OF THOSE MEMBERS AS POSSIBLE, BUT TO HAVE IT BE
17 EXACT WOULD PROBABLY UNDERMINE THE WHOLE CONCEPT OF
18 ACCELERATING.

19 CHAIRMAN THOMAS: THANK YOU FOR
20 CLARIFYING. I GUESS IT WOULD BE BEST EFFORTS TO
21 CONVENE AS MANY AS YOU COULD SO THAT YOU HAVE
22 CONTINUITY IN ANALYSIS AND DECISION-MAKING.

23 MR. SHEEHY: MR. JUELGAARD.

24 MR. JUELGAARD: SO I'M GOING TO INVOKE A
25 PROVISION OF ROBERTS RULES OF ORDER AT THIS POINT

BARRISTERS' REPORTING SERVICE

1 AND VOTE THAT WE OR I PROPOSE THAT WE LAY THIS
2 MOTION ON THE TABLE. WE TABLE THE MOTION. AND THE
3 REASON FOR DOING THAT IS THAT IF WE TABLE THE
4 MOTION, THEN I WANT TO PROPOSE A NEW MOTION IN WHICH
5 WE DECIDE ONE WAY THE OTHER WHETHER WE WISH TO
6 CHANGE THE PROCESS THAT WE HAVE NOW BECAUSE WE CAN
7 GO THROUGH A LOT OF MACHINATIONS HERE ABOUT SPECIFIC
8 DETAILS ONLY TO FIND OUT THAT THERE'S VERY LITTLE
9 SUPPORT FOR EVEN CHANGING THE CURRENT PROCESS THAT
10 WE HAVE. AND I'M NOT SURE THAT'S A GOOD USE OF OUR
11 TIME.

12 MR. SHEEHY: BEFORE I TAKE A SECOND ON
13 THAT, I DON'T THINK WE CAN CHANGE OUR PROCESS
14 WITHOUT NOTICE PER BAGLEY-KEENE. I'M LIKE 99
15 PERCENT. SO, MR. HARRISON.

16 MR. HARRISON: THAT'S CORRECT. WE CAN'T
17 MAKE A NEW POLICY THAT'S GENERALLY APPLICABLE
18 WITHOUT PROVIDING ADVANCE NOTICE. BY DEFINITION, IF
19 THE BOARD WERE TO APPROVE THE PREVIOUS MOTION, IT
20 WOULD APPLY SOLELY TO THIS APPLICATION.

21 WE COULD THEN, IF THE BOARD DESIRED, BRING
22 BACK A POLICY PROPOSAL AT THE NEXT MEETING, BUT WE
23 CANNOT DO THAT TODAY BECAUSE OF BAGLEY-KEENE.

24 DR. PRICE: SO WHAT YOU'RE SAYING, JAMES,
25 IS THAT WE CAN CHANGE POLICY WITHOUT NOTIFICATION.

BARRISTERS' REPORTING SERVICE

1 WE JUST CAN'T MAKE POLICY WITHOUT NOTIFICATION.
2 THAT'S PRETTY WEIRD.

3 MR. SHEEHY: I THINK WHAT HE'S SAYING IS
4 THAT THE BOARD HAS THE ABILITY TO TAKE WHAT ACTION
5 IT WANTS RELATIVE TO AN APPLICATION THAT'S IN FRONT
6 OF US. BUT THAT TAKING ACTION DOES NOT MAKE NEW
7 POLICY, NOR CAN WE DECIDE TO MAKE NEW POLICY
8 ARBITRARILY WITHOUT NOTICE BEFORE WE TAKE UP -- WE
9 TAKE ACTION ON A GRANT.

10 SO JUST TO BE CLEAR ON THE MOTION, BECAUSE
11 WE STILL -- I'M SORRY. THE MOTION TO TABLE TO TAKE
12 UP THE OTHER I DON'T THINK IS AN ALLOWABLE MOTION.
13 WE COULD HAVE A MOTION TO TABLE, JUST TO TABLE THE
14 MOTION, WHICH I THINK WOULD CUT OFF DISCUSSION ON IT
15 ALTOGETHER AND PUT IT OFF TO A LATER DATE, IF I'M
16 CORRECT.

17 MR. HARRISON: SO THE MOTION TO TABLE MADE
18 BY MR. JUELSGAARD, IF IT IS SECONDED, TAKES
19 PRECEDENCE OVER THE PENDING MOTION. AND IF THE
20 MOTION TO TABLE IS APPROVED BY THE BOARD, THEN YOU
21 ARE CORRECT, THAT THE PREVIOUS MOTION WOULD BE SET
22 ASIDE.

23 MR. SHEEHY: AND THEN WE WOULD BE AT A
24 POINT -- WHAT HAPPENS AFTER THAT?

25 MR. HARRISON: THE --

BARRISTERS' REPORTING SERVICE

1 MR. JUELSGAARD: THERE MIGHT BE A NEW
2 MOTION.

3 MR. HARRISON: THE MATTER COULD BE BROUGHT
4 BACK EITHER LATER TODAY OR AT A SUBSEQUENT MEETING.

5 MR. SHEEHY: SO WE COULD IMMEDIATELY GO
6 INTO A NEW MOTION AFTER THAT? I'M JUST TRYING TO
7 THINK ABOUT THE PROCESS BECAUSE DOESN'T THE TABLE
8 JUST KIND OF STOP THE CLOCK?

9 MR. HARRISON: THE TABLE STOPS THE CLOCK.
10 WHAT I WOULD RECOMMEND IS I WOULD LIKE TO CONSULT
11 OUR FRIENDS, ROBERTS RULES OF ORDER, FOR THE NEXT
12 STEPS IF THIS MOTION IS APPROVED. I BELIEVE THERE
13 IS SOME PERIOD OF TIME BEFORE WHICH THE MOTION CAN
14 BE RESURRECTED, BUT I'D LIKE TO DOUBLE-CHECK THAT
15 WITH MY COLLEAGUE.

16 DR. PRICE: POINT OF INFORMATION. THIS IS
17 THE FIRST TIME IN THE HISTORY OF ICOC MEETINGS THAT
18 JAMES HAS BEEN STUMPED.

19 MS. WINOKUR: WOULD YOU PLEASE REPEAT THE
20 MOTION?

21 MR. SHEEHY: WE HAVEN'T GOTTEN A SECOND ON
22 THE MOTION TO TABLE. SO THAT AT LEAST, UNLESS
23 SOMEBODY JUMPS UP AND SECONDS, IS NOT OPERATIVE.
24 SO --

25 MR. JUELSGAARD: WANT ME TO RESTATE THE

BARRISTERS' REPORTING SERVICE

1 MOTION?

2 MR. SHEEHY: I THINK IT'S UP TO --

3 MR. JUELGAARD: THE MOTION TO TABLE DR.
4 DULIEGE'S MOTION.

5 DR. DULIEGE: ARE PEOPLE ASKING ME TO
6 RESTATE THE INITIAL MOTION SO THAT PEOPLE UNDERSTAND
7 WHERE WE ARE? THAT IS COMPLETELY FINE.

8 MR. SHEEHY: CAN I JUST, NOT TO GET ALL
9 COMPLEX. SO THE MOTION TO TABLE LANGUAGE IS WITHOUT
10 A SECOND. DR. DULIEGE WILL RESTATE THE MOTION. I
11 THINK THAT THESE INGREDIENTS SHOULD BE INCLUDED IN
12 THE MOTION, PLEASE. WHO'S GOING TO REVIEW, WHETHER
13 IT'S THE FULL GRANTS WORKING GROUP, AND THEN ALSO
14 WHETHER IT COMES BACK TO THE BOARD, IF THOSE ARE
15 ELEMENTS, BUT THESE THINGS THAT WERE NOT ADDRESSED,
16 AND TIME FRAME AS WELL.

17 CHAIRMAN THOMAS: MR. SHEEHY, BEFORE DR.
18 DULIEGE DOES THAT, MR. JUELGAARD'S MOTION, IF
19 SECONDED, WOULD REQUIRE A VOTE AS TO TABLING,
20 CORRECT?

21 MR. TORRES: NO DEBATE.

22 MR. SHEEHY: NO DEBATE.

23 MR. TORRES: NO DEBATE ON A MOTION TO
24 TABLE. IT REQUIRES A SECOND AND THEN IT GOES TO A
25 VOTE.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN THOMAS: AND IF THE VOTE IS YES,
2 THEN --

3 MR. TORRES: MOTION GOES TO THE TABLE, AND
4 THEN APPARENTLY MR. JUELSGAARD HAS AN INTENT TO
5 INTRODUCE ANOTHER MOTION, OR THE OTHER OPTION WOULD
6 BE TO REMOVE THAT MOTION FROM THE TABLE.

7 CHAIRMAN THOMAS: MR. JUELSGAARD, IS THAT
8 CORRECT, YOU HAVE ANOTHER MOTION IN MIND?

9 MR. JUELSGAARD: YES, I DO. IF THIS
10 MOTION WERE TO BE TABLED, I WOULD PROPOSE ANOTHER
11 MOTION.

12 MR. PANETTA: SO ARE WE FOCUSED ON MR.
13 JUELSGAARD'S MOTION RIGHT NOW?

14 MR. SHEEHY: WE DON'T HAVE A SECOND, AND
15 I'M REALLY HOPING WE DON'T GET A SECOND. WITH ALL
16 DUE RESPECT, MR. JUELSGAARD, IT SEEMS LIKE A RABBIT
17 HOLE I DON'T REALLY WANT TO CRAWL DOWN. I THINK IT
18 WOULD BE GREAT TO HEAR DR. DULIEGE'S MOTION
19 RESTATED.

20 MR. TORRES: I WOULD LIKE TO GIVE HIM A
21 SECOND JUST TO HEAR WHAT HE HAS IN MIND.

22 MR. SHEEHY: ONE AT A TIME. RECOGNITION
23 BY THE CHAIR. AND THE POINT WE'RE AT RIGHT NOW IS
24 DR. DULIEGE WILL RESTATE HER MOTION.

25 CHAIRMAN THOMAS: ARE YOU SECONDING, MR.

BARRISTERS' REPORTING SERVICE

1 SENATOR?

2 MR. SHEEHY: WE DON'T HAVE A SECOND.

3 MR. TORRES: I WILL SECOND MR.

4 JUELSGAARD'S MOTION TO SEE WHAT HE HAS TO OFFER.

5 MR. SHEEHY: JUST IN TERMS OF RECOGNIZING
6 PEOPLE, I HAD RECOGNIZED DR. DULIEGE. THE MOTION
7 HAD NOT RECEIVED A SECOND WHEN I MADE THAT
8 RECOGNITION. SO COULD I PLEASE GET THIS MOTION
9 RESTATED. AND CAN PEOPLE KIND OF SPEAK WHEN THEY'RE
10 RECOGNIZED AND RAISE THEIR HAND TO LET ME KNOW.

11 DR. DULIEGE: WELL, IT'S CERTAINLY THE
12 FIRST TIME I JUST MADE A CONTROVERSIAL MOTION, AND
13 LITTLE DID I KNOW I WOULD GET INTO SUCH A DEBATE
14 ABOUT THE PROCESS, BUT IT'S ALWAYS GOOD TO DO NEW
15 THINGS. SO I'M GOING TO TRY TO RESTATE MY MOTION.

16 I MAKE THE MOTION THAT THIS PARTICULAR
17 APPLICATION GOES BACK TO THE GRANT WORKING GROUP
18 UNDER AN ACCELERATED PROCESS, AND THAT IT WILL THEN
19 COME BACK TO THE BOARD.

20 MR. SHEEHY: IS THAT SUFFICIENT BOTH FOR
21 COUNSEL AND FOR THE CIRM TEAM? IS THAT SUFFICIENT
22 DIRECTION?

23 MR. HARRISON: SO I THINK THE CIRM TEAM
24 WOULD APPRECIATE SOME ADDITIONAL DETAIL. IF I
25 COULD, PERHAPS I COULD TRY TO ARTICULATE IT. SO IT

BARRISTERS' REPORTING SERVICE

1 WOULD BE TO DEFER CONSIDERATION OF THIS APPLICATION
2 PENDING AN ACCELERATED REVIEW BY THE GWG OF THE
3 MATERIAL NEW INFORMATION PROVIDED BY THE APPLICANT
4 IN ORDER TO ADVISE THE APPLICATION REVIEW
5 SUBCOMMITTEE WHETHER THE NEW INFORMATION CHANGES THE
6 GWG RECOMMENDATION.

7 DR. DULIEGE: SO WELL SAID. THANK YOU.

8 MR. SHEEHY: IS THERE A SECOND?

9 MR. PANETTA: I'LL SECOND THAT MOTION.

10 MR. SHEEHY: SO, MR. JUELSGAARD, IF YOU
11 WANT TO OFFER YOUR MOTION.

12 MR. JUELSGAARD: I MOVE TO TABLE THE
13 MOTION.

14 MR. SHEEHY: DO WE HAVE A SECOND?

15 MR. TORRES: MR. CHAIRMAN, I WOULD ARGUE
16 THAT THE DISCUSSION OF MR. JUELSGAARD'S IDEA MIGHT
17 VERY WELL TAKE PLACE DURING THE DEBATE ON THIS
18 MOTION RATHER THAN TABLING IT.

19 MR. SHEEHY: MR. JUELSGAARD.

20 MR. JUELSGAARD: I'M JUST WAITING FOR A
21 SECOND. IF THERE IS NO SECOND, THE MOTION TO TABLE
22 DOESN'T PROCEED.

23 MR. TORRES: I UNDERSTAND THAT, BUT MY
24 REQUEST WAS CAN WE DISCUSS THE IDEA IN THE CONTEXT
25 OF THIS MOTION DURING THIS DEBATE.

BARRISTERS' REPORTING SERVICE

1 MR. JUELSGAARD: SURE. MY IDEA IS A VERY
2 SIMPLE ONE, WHICH IS THAT WE DON'T DEVIATE FROM THE
3 PRACTICE WE'VE JUST PUT IN PLACE NOT THAT LONG AGO,
4 WHETHER IN A SPECIAL EXCEPTION CIRCUMSTANCE LIKE
5 THIS, WHICH I BELIEVE WILL CREATE A LOT OF OTHER
6 SPECIAL EXCEPTIONAL CIRCUMSTANCES, I THINK THAT WAS
7 DR. LUBIN'S POINT, AND WE'LL BE IN THIS ENDLESS
8 CHASE-OUR-TAIL KIND OF GAME. SO I AM JUST -- WE
9 MOVED FROM ONE PROCESS TO THIS PROCESS. FOR ME IT'S
10 A SIX-MONTH PERIOD OF TIME OF DELAY. IN THE GRAND
11 SCHEME OF DEVELOPING A PRODUCT, A DRUG, THAT'S A
12 VERY SMALL AMOUNT OF DELAY. IT'S A TEN-YEAR PROCESS
13 ALTOGETHER MOST LIKELY.

14 SO I THINK -- SO WHAT I WAS GOING TO
15 PROPOSE IS THAT WE DON'T DEVIATE FROM OUR CURRENT
16 PROCESS. AND IF THE TEAM THAT PRESENTED THIS
17 APPLICATION BELIEVES THEY HAVE THE ANSWERS THAT THE
18 GWG WERE SEEKING, THEY COULD COME BACK AND SUBMIT
19 THAT WITH THE JULY NEW APPLICATIONS, AND THAT WOULD
20 BE REVIEWED IN OCTOBER, IF I REMEMBER THE DATES
21 RIGHT.

22 MR. SHEEHY: SENATOR TORRES.

23 MR. TORRES: I WOULD ADVISE MR. JUELSGAARD
24 THAT HE COULD PROVIDE A SUBSTITUTE MOTION WITHOUT
25 GOING THROUGH THE TABLING OF HIS IDEA AND THEN MOVE

BARRISTERS' REPORTING SERVICE

1 FORWARD EITHER UP OR DOWN AND THEN RETURN TO THE
2 PREVIOUS MOTION. THAT'S AN OPTION.

3 MR. JUELSGAARD: I WOULD HAVE TO DEFER TO
4 OUR COUNSEL ON THAT.

5 MR. SHEEHY: MIGHT I -- DOESN'T THE CHAIR
6 HAVE SOME AUTHORITY TO JUST GO AHEAD AND HAVE THIS
7 FIRST MOTION HEARD BECAUSE IT'S EFFECTIVELY THE SAME
8 THING. IF THIS MOTION FAILS, YOU WILL HAVE
9 ACCOMPLISHED WHAT YOU WANTED TO DO.

10 DR. PRICE: POINT OF ORDER. I BELIEVE
11 THAT IF THE SECOND -- IF THE NEW MOTION WAS ON THE
12 TABLE, THAT'S A MATTER OF BOARD PROCEDURE, WHICH THE
13 BOARD AS A WHOLE CAN VOTE ON AND NOT JUST THOSE ON
14 THE APPLICATION REVIEW COMMITTEE BECAUSE IT WOULD
15 NOT BE A REVIEW OF AN APPLICATION.

16 MR. HARRISON: THAT WOULD BE TRUE, BUT THE
17 PROBLEM WE HAVE IS THAT THE POLICY DISCUSSION WAS
18 NOT AGENDIZED. THERE WAS NO NOTICE OF IT. AND
19 UNDER BAGLEY-KEENE THIS BOARD CAN'T TAKE ACTION ON
20 AN ITEM THAT HAS NOT BEEN AGENDIZED, WHICH IS WHY,
21 IN MY ANSWER TO MR. SHEEHY EARLIER, I SPECIFIED THAT
22 THE ONLY THING THE BOARD WOULD BE CONSIDERING HERE
23 WOULD BE HOW TO TREAT THIS PARTICULAR APPLICATION AS
24 A ONE-OFF. IT WOULD NOT HAVE ANY IMPLICATIONS, NOR
25 WOULD IT APPLY TO ANY OTHER APPLICATION.

BARRISTERS' REPORTING SERVICE

1 IF THE BOARD DESIRES TO TAKE UP THIS
2 QUESTION AS A POLICY MATTER, WE WILL HAVE TO
3 AGENDIZE IT FOR A SUBSEQUENT BOARD MEETING.

4 DR. PRICE: THE JUELSGAARD MOTION WOULD
5 SIMPLY BE TO AFFIRM AN EXISTING POLICY. DOES THAT
6 HAVE TO BE AGENDIZED? DID I STUMP YOU?

7 MR. HARRISON: YOU DID. HONESTLY, A
8 MOTION TO AFFIRM AN EXISTING POLICY REALLY HAS NO
9 EFFECT BECAUSE THE EXISTING POLICY IS WHAT IT IS.
10 IT'S ALMOST AN ADVISORY MOTION. SO HONESTLY, I
11 WOULD HAVE TO TAKE A FEW MINUTES AND CONSULT WITH
12 ROBERTS RULES AND OUR FRIENDS BAGLEY AND KEENE AND
13 ADVISE YOU ABOUT HOW TO PROCEED IF THAT'S THE
14 DIRECTION YOU WANT TO GO.

15 MR. SHEEHY: SO I ACTUALLY THINK, TOO,
16 THAT WE WOULD HAVE TO ADJOURN THE APPLICATION REVIEW
17 SUBCOMMITTEE AND MEET AS THE BOARD AS A WHOLE IN
18 ORDER TO TAKE UP THAT MOTION. AND IF THAT'S WHAT
19 PEOPLE WANT TO DO, BUT THEN WE'LL STILL HAVE TO COME
20 BACK AND TAKE ACTION ON THESE GRANTS. AND THAT
21 MOTION, ANYWAY, WOULD NOT HAVE ANY AUTHORITY ON THE
22 GRANT THAT WE HAVE UNDER CONSIDERATION ANYWAY.

23 THE MAKERS OF THE MOTION WITHIN THE
24 APPLICATION REVIEW SUBCOMMITTEE BRING THE GRANT BACK
25 UP WITH THE SAME MOTION THAT THEY JUST MADE, AND WE

BARRISTERS' REPORTING SERVICE

1 WOULD NEED TO CONSIDER IT AND VOTE ON IT. SO IF
2 EVERYONE IS COMFORTABLE IN MAYBE WALKING OUT OF THE
3 ROBERT'S RULES OF ORDER AND THE PROCESS WEEDS AND
4 MAYBE JUST GOING AHEAD AND CONSIDERING THIS
5 APPLICATION. I THINK IT'S IMPORTANT THAT PEOPLE
6 EXPRESS THEIR VIEWS ON THE MERITS, FOR ME
7 PERSONALLY, THAT PEOPLE EXPRESS THEMSELVES ON THE
8 MERITS OF THE MOTION AS OPPOSED TO THE PROCESS. THE
9 BOARD DOES HAVE THE ABILITY, A VERY BROAD RANGE OF
10 ABILITY, TO MAKE DECISIONS ON APPLICATIONS THAT COME
11 BEFORE US.

12 IN THAT CONTEXT, I'M HEARING VOICES THAT
13 THEY FEEL VERY UNCOMFORTABLE WITH CHANGING OUR
14 PROCESS. BUT THAT HAVING BEEN SAID, WE HAVE A
15 MOTION IN FRONT OF US. UNLESS THERE'S MORE BOARD
16 COMMENT, I WAS GOING TO TAKE PUBLIC COMMENT, BUT IS
17 THERE ANYTHING ELSE ANYONE WANTS TO ADD TO THE BOARD
18 DISCUSSION EITHER HERE OR ON THE PHONE? OKAY.

19 SO I'M TAKING -- I'LL TAKE PUBLIC COMMENT
20 NOW, AND THIS IS SPECIFIC TO THIS APPLICATION. THIS
21 IS NOT GENERAL. SO I ASK THAT THE SPEAKERS SPEAK TO
22 THIS APPLICATION AND THE MOTION BEFORE US. AND I
23 ALSO NOTE THAT WE HAVE A THREE-MINUTE LIMIT FOR
24 PUBLIC COMMENT.

25 DR. BRATT-LEAL: MY NAME IS ANDRES

BARRISTERS' REPORTING SERVICE

1 BRATT-LEAL, AND I'VE BEEN WORKING ON THIS PROJECT
2 WITH DR. LORING SINCE THE BEGINNING. I HELP BIOPSY
3 THE PATIENTS AND REPROGRAM THE CELL LINES. AND NOW
4 I'M SENIOR SCIENTIST WORKING WITH DR. LORING FOR THE
5 CENTER FOR STEM CELL ADVOCACY PROJECT.

6 I'M NOT GOING TO GO THROUGH AND TALK ABOUT
7 EACH OF THE INDIVIDUAL SCIENCE POINTS. IT SOUNDS
8 LIKE THE BOARD DOESN'T REALLY WANT ME TO DO THAT.
9 WHAT I DO WANT TO POINT OUT IS IF THIS WAS A
10 DIFFERENT TYPE OF GRANT -- AND THE CIRM STAFF WAS
11 REALLY GREAT. GIL SAMBRANO WAS REALLY HELPFUL IN
12 EXPLAINING TO US WHAT OUR DIFFERENT OPTIONS ARE IN
13 TERMS OF REAPPLYING OR APPLYING FOR A DIFFERENT
14 GRANT. IF THIS WERE ANY OTHER PROJECT, I THINK THAT
15 WOULD BE FAIR, AND WE WOULD JUST LEAVE IT AT THAT,
16 AND WE WOULD APPLY FOR ANOTHER PROJECT.

17 BUT BECAUSE OUR PROJECT IS REALLY INVOLVED
18 WITH PATIENTS, AND SOME OF THE PATIENTS ARE HERE,
19 CENTER FOR STEM CELL IS A PATIENT ADVOCACY GROUP
20 THAT HAS RAISED ALL THE MONEY FOR THIS. WE FELT IT
21 WAS OUR OBLIGATION TO DO WHAT WE COULD TO MAKE THIS
22 GO FASTER. I KNOW THAT SIX MONTHS MAY NOT SOUND
23 LIKE A LOT IN THE TOTAL TIME SCHEME, BUT FOR THESE
24 PATIENTS IT ACTUALLY IS A LOT.

25 SO I THINK I'M NOT GOING TO ASK YOU TO

BARRISTERS' REPORTING SERVICE

1 LOOK AT THE INDIVIDUAL SCIENTIFIC POINTS, BUT WHAT I
2 THINK IS AN EXTRAORDINARY PART OF THIS IS THAT WE
3 DID MEET WITH THE FDA SIX DAYS AFTER THIS GRANT WAS
4 REVIEWED. AND A LOT OF WHAT THE FDA TOLD US WENT
5 AGAINST WHAT THE GRANTS WORKING GROUP SAYS. SO WITH
6 ALL RESPECT TO THE GRANTS WORKING GROUP, OUR GOAL IS
7 TO GET THIS PROJECT THROUGH THE FDA AS QUICKLY AS
8 POSSIBLE.

9 AND SO WE ACTUALLY -- ONE OF THE CONCERNS
10 OF THE GRANTS WORKING GROUP WAS THAT OUR ANIMAL
11 STUDY DIDN'T HAVE ENOUGH ANIMALS. WELL, THE FDA
12 DIDN'T SHARE THAT VIEW. SO BECAUSE IT'S A YEAR LONG
13 ANIMAL STUDY, WE PRIVATELY RAISED THE MONEY TO START
14 THAT STUDY IN FEBRUARY. AND SO WHAT WE'RE TRYING TO
15 DO IS MOVE FORWARD AS QUICKLY AS POSSIBLE. WE'RE
16 NOT ASKING FOR A BLANK CHECK FOR \$7.8 MILLION. WHAT
17 WE'RE ASKING FOR IS, TO USE THE TRAIN ANALOGY ONCE
18 AGAIN, WE'RE ASKING FOR A PROGRAMMATIC DECISION TO
19 ALLOW US TO GET ON THE TRAIN. AND THEN IF WE MEET
20 MILESTONES, WHICH WE'RE CONFIDENT THAT WE WILL, THEN
21 WE CAN MOVE FORWARD WITH DISBURSEMENTS FROM CIRM.
22 IF WE'RE NOT MEETING OUR MILESTONES, THEN WE'RE
23 HAPPY TO GET ESCORTED OFF THE TRAIN. THANKS.

24 MR. REED: DON REED, PATIENT ADVOCATE. MY
25 REASON FOR SUPPORTING THIS IS PROGRAMMATIC. I

BARRISTERS' REPORTING SERVICE

1 RECENTLY ADDRESSED OUR LOCAL HIGH SCHOOL, AND FOR
2 SIX PERIODS I STOOD ON MY FEET AND ANSWERED
3 QUESTIONS AND TALKED ABOUT WHAT YOU GUYS DO ALL THE
4 TIME. AND IT WAS A TIME OF GREAT PRIDE.

5 INTERESTINGLY, I ASKED EACH AUDIENCE WHAT
6 IS A CHRONIC DISEASE THAT YOU CAN NAME. IN EVERY
7 INSTANCE THEY NAMED ALZHEIMER'S AND THEY NAMED
8 PARKINSON'S. THIS IS A VERY WIDELY RECOGNIZED NEED
9 FOR A CURE. PEOPLE TALK ABOUT THE PAIN THAT THEIR
10 PEOPLE WENT THROUGH. ONE PERSON SAID THAT IT WAS
11 LIKE HAVING ARTHRITIS IN EVERY JOINT. IT'S
12 PROGRESSIVE. WE ALL KNOW OUR BELOVED ICOC MEMBER NO
13 LONGER WITH US AND HOW HARD SHE FOUGHT AND HOW THE
14 DISEASE GOT WORSE AND WORSE AND THE PAIN TOO GREAT
15 TO SUFFER. I THINK WE HAVE A LACK HERE. AND I
16 THINK THAT THE WORK THAT YOU'RE DOING HERE IS
17 EXTREMELY IMPORTANT. IT'S ALWAYS A JOY TO WATCH YOU
18 GUYS WORK THINGS OUT. I WISH WASHINGTON COULD SEE
19 THE WAY YOU DO IT AND IMITATE IT. I REALLY HOPE
20 THAT YOU SUPPORT THIS, FIND A WAY TO SUPPORT THIS.
21 THANK YOU.

22 MR. SHEEHY: IS THERE ADDITIONAL PUBLIC
23 COMMENT?

24 UNIDENTIFIED SPEAKER: YES, THERE IS DOWN
25 HERE IN SAN DIEGO.

BARRISTERS' REPORTING SERVICE

1 MR. SHEEHY: WE HAVE ONE MORE PERSON --
2 LET'S TAKE SAN DIEGO AND THEN WE'LL GO BACK TO THE
3 MIC HERE. REMEMBER, THREE MINUTES PER COMMENT. AND
4 THE PERSON WHO'S COMMENTING SHOULD SAY THEIR NAME.
5 IF THE SPELLING IS DIFFICULT, PLEASE SPELL IT FOR
6 OUR TRANSCRIBER.

7 MS. PETERS: MY NAME IS CASSANDRA PETERS.
8 MY FIRST NAME IS SPELLED C-A-S-S-A-N-D-R-A, AND THE
9 LAST NAME IS PETERS WITH A P, P-E-T-E-R-S.

10 I AM A PATIENT ADVOCATE OF THE
11 SUMMIT4STEMCELL PROJECT. AND I HAVE HAD PARKINSON'S
12 FOR AT LEAST 15 YEARS NOW. I HAD HOPED THAT MY 60TH
13 BIRTHDAY, WHICH JUST PASSED, WAS GOING TO BRING ME
14 WORD THAT OUR PROJECT WAS ON TRACK AND READY TO MOVE
15 INTO THE HOSPITAL FOR THE PROCEDURES. UNFORTUNATELY
16 I COME HERE AND I HEAR A WHOLE LOT OF DISCUSSION
17 THAT TO ME IS VERY IMPORTANT, BUT THERE ARE SEVEN
18 MILLION PEOPLE RIGHT NOW WITH THIS DISEASE. AND I
19 GOT TO TELL YOU YOUR ARBITRARILY DISCUSSING HOW MUCH
20 PAIN WE GO THROUGH CAN BE AFFECTING, BUT IT IS NOT
21 ILLOGICAL. AND LOGIC IS THAT THIS ENTIRE ENTITY WAS
22 FORMED TO HELP PATIENTS. YOU HAVE TEN PATIENTS
23 WAITING FOR THIS PROCEDURE, WAITING FOR THE SCIENCE
24 TO COME TO US.

25 I THANK YOU FOR ALL YOUR SUPPORT IN THE

BARRISTERS' REPORTING SERVICE

1 PAST. AND, DR. MILLS, I KNOW THAT YOU HAVE BEEN A
2 VERY STRONG SUPPORTER FOR ALL OF US. AND, SIR, I
3 HOPE THAT YOU WILL, IN TANDEM WITH THIS MARVELOUS
4 ENTITY THAT CALLS ITSELF SUMMIT4STEMCELL, I HOPE
5 THAT I GET THE OPPORTUNITY TO KNEEL IN FRONT OF YOU
6 AND SAY THANK YOU.

7 MR. SHEEHY: IS THERE ADDITIONAL PUBLIC
8 COMMENT IN SAN DIEGO?

9 MR. MADDOX: EIGHT YEARS AGO I WAS
10 DIAGNOSED --

11 MR. SHEEHY: I'M SORRY. I DON'T MEAN TO
12 INTERRUPT YOU, BUT WE NEED A NAME PLEASE. I'M
13 SORRY.

14 MR. MADDOX: MY NAME IS PHIL MADDOX, SAN
15 DIEGO. EIGHT YEARS AGO I WAS DIAGNOSED WITH
16 PARKINSON'S DISEASE, A DEGENERATIVE DISEASE.
17 CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE,
18 THERE'S A CONNECTION. OBVIOUSLY I HAVE A VESTED
19 INTEREST IN THIS, BUT AS A PATIENT ADVOCATE, THERE
20 ARE OVER ONE MILLION PARKINSON'S PATIENTS IN THE
21 U.S. ALONE. I'M NOT A SCIENTIST, NOR DO I HAVE AN
22 MBA, BUT I BEG YOU TO PLEASE CONSIDER THIS.

23 CLOSE TO A MILLION PARKINSON'S PATIENTS IN
24 THE U.S.A. ALONE COULD BENEFIT FROM THIS STEM CELL
25 RESEARCH. THIS THERAPY WOULD HELP AND IS SECOND

BARRISTERS' REPORTING SERVICE

1 ONLY TO ALZHEIMER'S, THE MOST EXPENSIVE, ALMOST \$20
2 MILLION ANNUAL BURDEN TO OUR NATIONAL HEALTHCARE
3 SYSTEM.

4 AS STEWARDS OF OUR TAXPAYER DOLLARS, IF
5 YOU ARE CONSIDERING FUNDING, I BEG YOU TO CONSIDER
6 OUR APPLICATION WHICH WOULD BENEFIT MILLIONS IN THE
7 U.S. ALONE. OUR RATS IN THE LABS ARE BEHAVING AS
8 PREDICTED. (INAUDIBLE) PLURIPOTENT STEM CELL
9 THERAPY IS A HIGHLY EFFECTIVE TREATMENT FOR
10 PARKINSON'S. THIS IS HAPPENING RIGHT NOW RIGHT HERE
11 IN LA JOLLA. HELP US BRING THIS RESEARCH TO THE
12 PEOPLE, OVER A MILLION PEOPLE, NOT TO FORGET THE
13 FAMILY MEMBERS, CAREGIVERS, AND OUR NATIONAL
14 HEALTHCARE SYSTEM THAT'S INVESTED IN THIS THERAPY.
15 THANK YOU FOR YOUR TIME.

16 MR. SHEEHY: THANK YOU. IS THERE
17 ADDITIONAL PUBLIC COMMENT FOR SAN DIEGO?

18 UNIDENTIFIED SPEAKER: NO. THAT'S IT.

19 MR. SHEEHY: GREAT. NOW WE HAVE PUBLIC
20 COMMENT IN SAN FRANCISCO CONTINUING.

21 MS. GOULD: YES. MY NAME IS SHERRIE
22 GOULD, AND I'VE HAD THE PRIVILEGE OF ADDRESSING THIS
23 GROUP ON A NUMBER OF DIFFERENT OCCASIONS. I AM A
24 CLINICIAN, A NURSE PRACTITIONER. THESE ARE OUR
25 PATIENTS AT SCRIPPS CLINIC.

BARRISTERS' REPORTING SERVICE

1 SO THERE'S A LOT OF THINGS I CAN SAY ABOUT
2 THIS, AND I CAN ADDRESS, OF COURSE, THE HORRORS OF
3 PARKINSON'S DISEASE. I CAN ADDRESS THE ISSUE THAT
4 DEEP BRAIN STIMULATION, WHICH WE DO A LOT OF AT
5 SCRIPPS CLINIC, AND THE MEDICATIONS ARE NOT WORKING
6 AS THESE YEARS GO ON FOR OUR PATIENTS. THESE
7 PATIENTS WE CHOSE FOUR OR FIVE YEARS AGO. SIX
8 MONTHS MEANS A HUGE AMOUNT TO THEM. IT MEANS I'M
9 GOING TO HAVE TO INCREASE THEIR MEDICATIONS OR
10 POSSIBLY INSIST THAT THEY GET DEEP BRAIN
11 STIMULATION. I CAN TALK ABOUT THE COMMUNITY
12 INVOLVEMENT OF THIS PROJECT AROUND THE WORLD OF
13 PEOPLE BEING INVOLVED, OF RAISING MONEY, OF DOING
14 BIKE RIDES, CLIMBING MOUNTAINS, ETC., ETC.

15 I CAN ALSO SPEAK TO THE FACT THAT
16 SUMMIT4STEMCELL HAS BEEN COMMITTED TO FUNDING THIS
17 PROJECT, WHICH WE'VE DONE THUS FOR THE LAST FIVE
18 YEARS. WE HAVE DONE EVERYTHING POSSIBLE TO GET
19 US -- ALREADY WE DID OUR PRE-PRE IND WITH THE FDA.
20 HUGE. AND WE'VE DONE IT WITH THE BLOOD, SWEAT, AND
21 TEARS OF JUST PATIENTS AND PATIENT ADVOCATES. IT'S
22 BEEN A PRETTY PHENOMENAL PROJECT.

23 BUT ALL THAT BEING SAID, THE MOST
24 IMPORTANT THING OF ALL OF THIS IN YOUR CONSIDERATION
25 OF EXPEDITING A REVIEW OR HAVING THE GRANT'S WORKING

BARRISTERS' REPORTING SERVICE

1 GROUP TAKE A LOOK AT THIS SOONER IS THAT THE SCIENCE
2 ITSELF IS VALID. THE NEW INFORMATION THAT WE HAVE
3 GOTTEN SINCE WE SUBMITTED THAT APPLICATION ON
4 NOVEMBER 20TH IS SIGNIFICANT. IT'S NOT JUST A
5 LITTLE OPINION. IT'S FDA SIGNIFICANT. IT'S
6 PUBLICATION SIGNIFICANT. AND, AGAIN, SIX MONTHS IN
7 THE LIVES OF A PERSON WITH PARKINSON'S IS ALSO
8 SIGNIFICANT. THANK YOU VERY MUCH FOR YOUR TIME.

9 MS. HAWKINS: HI. MY NAME IS MARYROSE
10 HAWKINS MULVEY. AND I HEARD ABOUT SUMMIT4STEMCELL
11 THROUGH MY PATIENT, JEANNE LORING. UNFORTUNATELY I
12 DIDN'T REALLY KNOW WHAT SHE WAS DOING UNTIL THERE
13 WERE TEN OTHER PATIENTS THAT WERE TAKEN, BUT MY
14 HUSBAND AND I ARE HERE BECAUSE THESE PEOPLE ARE
15 AMAZING PEOPLE. I THINK THE SCIENCE, AGAIN, IS
16 GOING TO HAPPEN AT SOME POINT. BUT AS WITH MY
17 HUSBAND HAVING PARKINSON'S DIAGNOSED TEN YEARS AGO,
18 I FEEL LIKE TIME IS OF THE ESSENCE.

19 AND I KNOW THAT ALL THESE OTHER DISEASES,
20 AND I'M SO GRATEFUL TO YOU ALL FOR LISTENING TO
21 THIS, AND SO GRATEFUL TO HEAR ABOUT MUSCULAR
22 DYSTROPHY BECAUSE MY HUSBAND'S BROTHER DIED 20 YEARS
23 AGO FROM DUCHENNE'S. SO YOU ALL ARE DOING AMAZING
24 WORK. AND I THINK IF THERE'S ANY WAY THAT WE CAN
25 GET THIS RESEARCH COMPLETED, MAYBE MY HUSBAND CAN

BARRISTERS' REPORTING SERVICE

1 ALSO GET ONTO THE TRAIN. WE'RE OBSERVERS NOW, BUT
2 THESE ARE AMAZING PEOPLE. AND I HOPE WE CAN ALL DO
3 SOMETHING FOR THEM. THANK YOU SO MUCH.

4 MR. SHEEHY: ADDITIONAL PUBLIC COMMENT?

5 MS. RAUB: HELLO. HOW IS EVERYBODY? THIS
6 IS QUITE AN INTERESTING CHANGE, ISN'T IT? MY NAME
7 IS JENIFER RAUB, AND I'VE HAD PARKINSON'S. I WAS
8 DIAGNOSED ABOUT EIGHT YEARS AGO. I HONESTLY THINK
9 I'VE HAD IT SINCE I WAS 35. I HAVE THIS SO I DON'T
10 CRY. BUT A FUTURE WITHOUT STEM CELL IS FRIGHTENING.
11 SORRY. AND PLEASE SUPPORT THIS. WE'VE WAITED --
12 SUMMIT4STEMCELL -- I'M SO EMOTIONAL RIGHT NOW. I'M
13 SORRY.

14 RIGHT HERE IN THE STATE OF CALIFORNIA,
15 THIS RESEARCH EXISTS. WE ARE GLOBAL LEADERS IN
16 THIS. AND WITH YOUR SUPPORT, WE CAN KEEP THIS ON
17 TARGET TO FILING THE APPLICATION WITH THE FDA IN THE
18 FIRST QUARTER OF 2018. WITHOUT HELP, WE'RE NOT --
19 I'LL BE SURPRISED IF WE CAN MAKE THIS TARGET. I GET
20 CALLS FROM ALL OVER THE WORLD AND ALL OVER THE
21 COUNTRY ASKING ABOUT THIS RESEARCH. I HAD SOMEBODY
22 FROM GERMANY CALL ME THE OTHER DAY, AND
23 PHARMACEUTICAL COMPANIES IN GERMANY ARE ASKING HIM
24 ABOUT US.

25 WE NEED YOUR SUPPORT TO HELP SO MANY

BARRISTERS' REPORTING SERVICE

1 PEOPLE LIKE MYSELF TO HAVE A FUTURE WITHOUT FEAR, TO
2 HAVE A FUTURE WITH HOPE. THANK YOU VERY MUCH FOR
3 ALL THAT YOU DO FOR THIS INDUSTRY.

4 MR. SHEEHY: THANK YOU. AND THANK YOU TO
5 YOU ALL. I BELIEVE, IS THAT IT FOR PUBLIC COMMENT?
6 I JUST WANT TO THANK EVERYBODY FOR SHARING THEIR
7 STORIES. IT'S VERY POWERFUL, AND I KNOW IT TAKES A
8 LOT TO DO THIS.

9 AND AT THIS POINT I THINK WE'RE READY TO
10 CALL THE ROLL. MR. HARRISON, DO YOU HAVE THE MOTION
11 IN FRONT OF YOU WHERE YOU MIGHT BE ABLE TO RESTATE
12 IT FOR THE MEMBERS BEFORE WE VOTE?

13 MR. HARRISON: THE MOTION IS TO DEFER
14 CONSIDERATION OF THIS APPLICATION, WHICH IS 08468,
15 PENDING AN ACCELERATED REVIEW BY THE GWG OF THE
16 MATERIAL NEW INFORMATION PROVIDED BY THE APPLICANT
17 IN ORDER TO ADVISE THE APPLICATION REVIEW
18 SUBCOMMITTEE WHETHER THE NEW INFORMATION CHANGES THE
19 GWG RECOMMENDATION.

20 CHAIRMAN THOMAS: CAN I ASK A QUESTION?
21 DR. MILLS, KNOWING THAT THERE ARE SOME LOGISTICS TO
22 RECONVENING GROUPS, IN YOUR OPINION, I KNOW THERE
23 HAVE BEEN A RANGE, HOW LONG DO YOU THINK IT WOULD
24 TAKE TO PULL TOGETHER THE GWG FOR EXPEDITED REVIEW
25 TAKING INTO ACCOUNT GETTING AHOLD OF THEM, THEM

BARRISTERS' REPORTING SERVICE

1 HAVING TO REVIEW, ALL THAT SORT OF THING, WHAT ARE
2 WE TALKING ABOUT?

3 DR. MILLS: I WOULD THINK THE FIRST
4 QUESTION I STILL HAVE A LITTLE BIT ABOUT THE PROCESS
5 IS EXACTLY WHAT MATERIAL WE'RE GOING TO HAVE THEM
6 RE-REVIEW AND WHAT FORMAT THAT'S GOING TO COME TO
7 US, WHETHER OR NOT IT'S JUST GOING TO BE SOME
8 LETTERS THAT HAVE BEEN GIVEN TO US OR WHETHER OR NOT
9 THEY'RE ACTUALLY GOING TO AMEND THEIR APPLICATION TO
10 PUT THAT NEW MATERIAL IN. ONCE THEY GET THAT
11 APPLICATION IN, WE USUALLY GIVE THE REVIEWERS A FAIR
12 AMOUNT OF TIME TO REVIEW IT. SO WHENEVER WE HOLD A
13 DATE, WE LIKE TO GIVE THEM SOMEWHERE ALONG THE LINES
14 OF 14 TO 21 DAYS WHERE THEY HAVE THE MATERIAL IN
15 THEIR HANDS SO THEY CAN GO THROUGH IT AND GO THROUGH
16 A FAIR AND VALID VETTING PROCESS.

17 YOU IMAGINE WE CAN PULL A GWG TOGETHER --

18 DR. JORGENSON: TO CONDUCT THE REVIEW, HOW
19 LONG TO CONDUCT THE REVIEW AND GIVE THEM TIME TO
20 CONDUCT THE REVIEW? TWO MONTHS.

21 DR. MILLS: TWO MONTHS.

22 MR. SHEEHY: THANK YOU. MS. BONNEVILLE,
23 ARE YOU PREPARED TO CALL THE ROLL.

24 MS. BONNEVILLE: ANNE-MARIE DULIEGE.

25 DR. DULIEGE: YES.

BARRISTERS' REPORTING SERVICE

1 MS. BONNEVILLE: DAVID HIGGINS.
2 DR. HIGGINS: YES.
3 MS. BONNEVILLE: STEVE JUELSGAARD.
4 MR. JUELSGAARD: NO.
5 MS. BONNEVILLE: SHERRY LANSING. KATHY
6 LAPORTE.
7 MS. LAPORTE: NO.
8 MS. BONNEVILLE: LAUREN MILLER.
9 MS. MILLER: YES.
10 MS. BONNEVILLE: ADRIANA PADILLA.
11 DR. PADILLA: YES.
12 MS. BONNEVILLE: JOE PANETTA.
13 MR. PANETTA: YES.
14 MS. BONNEVILLE: FRANCISCO PRIETO. ROBERT
15 QUINT.
16 DR. QUINT: NO.
17 MS. BONNEVILLE: AL ROWLETT.
18 MR. ROWLETT: YES.
19 MS. BONNEVILLE: JEFF SHEEHY.
20 MR. SHEEHY: ABSTAIN.
21 MS. BONNEVILLE: OS STEWARD.
22 DR. STEWARD: ABSTAIN.
23 MS. BONNEVILLE: JONATHAN THOMAS.
24 CHAIRMAN THOMAS: NO.
25 MS. BONNEVILLE: DIANE WINOKUR.

BARRISTERS' REPORTING SERVICE

1 MS. WINOKUR: YES.

2 MR. HARRISON: MOTION PASSES BY A VOTE OF
3 EIGHT YES, FOUR NO, AND TWO ABSTENTIONS.

4 MR. SHEEHY: SO NOW I'LL TAKE ANY MOTIONS
5 TO MOVE ANYTHING OUT OF TIER II INTO TIER I.
6 THERE'S NO MOTIONS. I'LL TAKE AN OMNIBUS MOTION TO
7 FUND ALL OF THE APPLICATIONS THAT ARE IN TIER I,
8 WHICH NOW INCLUDES THE APPLICATION WE JUST VOTED ON,
9 AND IT DOES NOT INCLUDE THE APPLICATION THAT'S BEEN
10 DEFERRED FOR FUTURE ACTION, WHICH IS --

11 MR. HARRISON: 8522.

12 MR. SHEEHY: -- 8522. AND 8468 IS NOW
13 PART OF TIER I.

14 SO I NEED A MOTION FROM SOMEONE, I THINK,
15 WITHOUT CONFLICTS. IS THAT TRUE, JAMES?

16 AND COULD I GET A SECOND? SECOND BY --

17 THE REPORTER: COULD YOU TELL ME WHO MADE
18 THE MOTION?

19 MR. SHEEHY: YES. DR. LAPORTE MADE THE
20 MOTION, AND MS. MILLER MADE THE SECOND TO THE
21 MOTION.

22 MR. HARRISON: JUST TO BE CLEAR, THE
23 APPLICATION 8468 WILL BE PRESENTED --

24 MR. SHEEHY: BOTH OF THESE ARE DEFERRED
25 ACTION. LET'S AMEND THE MOTION. LET'S BE CLEAR

BARRISTERS' REPORTING SERVICE

1 ABOUT THE MOTION, THE MAKERS ARE BOTH CLEAR ON THIS.
2 THESE TWO APPLICATIONS WILL BE DEFERRED FOR LATER
3 ACTION. EVERYTHING IN TIER I, THE SEVEN
4 APPLICATIONS IN TIER I, ARE FUNDED, AND ALL THE
5 APPLICATIONS IN TIER II REMAINING ARE NOT FUNDED.
6 THAT'S CLEAR. BOTH MAKERS, DR. LAPORTE AND MS.
7 MILLER, ARE IN AGREEMENT. ANY BOARD COMMENT ON THIS
8 MOTION? IS THERE PUBLIC COMMENT?

9 DR. CHIU: ARLENE CHIU, CITY OF HOPE. I
10 JUST WANTED TO MAKE A COMMENT ABOUT THE RANGE OF
11 PROPOSALS. I CONGRATULATE CIRM FOR THIS INITIATIVE
12 BECAUSE YOU HAVE IDENTIFIED A LOT OF TRAN1 PROPOSALS
13 THAT ARE READY TO GO, AND THAT'S EXCELLENT NEWS.

14 IT OCCURRED TO ME, JUST LOOKING AT ALL THE
15 PROPOSALS, THAT THERE ARE NO PROPOSALS FROM TRAN2,
16 3, OR 4 THAT HAVE BEEN RECOMMENDED FOR FUNDING. AND
17 I KNOW THEY'RE SIGNIFICANT PARTS OF YOUR INITIATIVE.
18 SO THIS IS JUST A GENERAL COMMENT, THAT IT SEEMS TO
19 ME THAT PUTTING IN TOOLS AND TECHNOLOGY INTO THIS
20 PARTICULAR INITIATIVE MAY NOT BE THE BEST WAY TO TRY
21 TO GET FUNDING FOR CERTAIN KINDS OF TECHNOLOGIES
22 THAT MIGHT BE VERY IMPORTANT FOR TRANSLATION, BUT
23 NOT FIT THE BILL AS DESCRIBED IN THIS INITIATIVE.

24 AND LET ME JUST SAY THAT PROP 71, AND CIRM
25 PARTICULARLY, IS BASED ON TECHNOLOGIES SUCH AS JAMIE

BARRISTERS' REPORTING SERVICE

1 THOMSON'S TECHNOLOGY OF GENERATING HUMAN EMBRYONIC
2 STEM CELLS AND ON SHINYA YAMANAKA'S GROUNDBREAKING
3 TECHNOLOGY OF GENERATING INDUCED PLURIPOTENT STEM
4 CELLS. WITHOUT THOSE TWO, THERE WOULD NOT HAVE
5 BEEN, WELL, AT LEAST WITHOUT JAMIE THOMSON'S WORK,
6 THERE WOULD NOT HAVE BEEN A PROP 71 AND WHERE WE ARE
7 TODAY, AND THIS HAS BEEN A GREAT INITIATIVE.

8 SO I JUST WANTED TO SUGGEST THAT PERHAPS
9 THERE ARE NEW TECHNOLOGIES THAT MAY NOT BE
10 COMMERCIALIZABLE, JUST LIKE SHINYA YAMANAKA'S IS NOT
11 COMMERCIALIZED, IT'S JUST OPEN FOR EVERYBODY TO USE,
12 BUT MIGHT SERVE THE FIELD VERY WELL AND ACCELERATE
13 TRANSLATION IN MANY DISEASES RATHER THAN HAVING TO
14 IDENTIFY A SPECIFIC DISEASE.

15 SO I NOTE THAT TRAN4, THE BEST TRAN4
16 PROPOSAL, HAS A SCORE OF 79, BUT IT SUFFERS FROM
17 INABILITY TO COMMERCIALIZE IT OR NOT DESCRIBED. I
18 WAS HOPING THAT THERE MIGHT BE AN AVENUE IN FUTURE
19 INITIATIVES TO GIVE THIS KIND OF PROPOSAL SOME
20 LEVERAGE. THANK YOU.

21 MR. SHEEHY: ADDITIONAL PUBLIC COMMENT?
22 AGAIN, THREE MINUTES IS THE LIMIT FOR PUBLIC
23 COMMENT.

24 DR. KREMEN: MY NAME IS THOMAS KREMEN.
25 I'M AN ORTHOPEDIC SURGEON AT CEDARS-SINAI MEDICAL

BARRISTERS' REPORTING SERVICE

1 CENTER. I JUST WANTED TO READ A FEW COMMENTS I'VE
2 WRITTEN DOWN ABOUT TRAN1-08527. IT'S THE ULTRASOUND
3 MEDIATED STEM CELL ACTIVATION THERAPY FOR TENDON AND
4 LIGAMENT INJURIES. I'LL RESPECT THE TIME FRAME AND
5 KEEP THIS UNDER THREE MINUTES.

6 WE RECEIVED A MEDIAN SCORE OF 85, AND AN
7 OVERALL SCORE OF 83, AND SEVEN OF OUR REVIEWERS
8 SOUGHT FAVORABLY ON THIS APPLICATION. BUT I'D JUST
9 LIKE TO LEAVE SOME COMMENTS ADDRESSING THE CLINICAL
10 IMPACT AND THE TRANSLATIONAL ASPECTS OF THIS.

11 EVEN WHEN USING MODERN SURGICAL
12 TECHNIQUES, LIGAMENT RECONSTRUCTIONS HEAL TO BONE
13 VIA SCAR TISSUE. AND THIS IS BIOMECHANICALLY
14 INFERIOR TO NORMAL LIGAMENT INSERTIONS. THIS
15 IRREGULAR STRUCTURE REALLY LEADS TO AN INCREASE IN
16 THE FAILURE RATE AND REPRESENTS A SIGNIFICANT UNMET
17 CLINICAL NEED FOR OUR POPULATION.

18 THE ABOVE PROPOSAL THAT I MENTIONED REALLY
19 AIMS TO IMPROVE THIS INTERFACE, AND WE CAN AUGMENT
20 SURGERY SUCH THAT WE RECAPITULATE THE NORMAL ANATOMY
21 AGAIN. THE ABILITY TO STIMULATE THIS PROCESS HAS A
22 REAL ADVANTAGE BECAUSE IT'S MINIMALLY INVASIVE AND
23 IT'S A TECHNOLOGY THAT'S AMENABLE TO EXPEDITED FDA
24 APPROVAL.

25 JUST TO GIVE YOU SOME BACKGROUND, ANTERIOR

BARRISTERS' REPORTING SERVICE

1 CRUCIATE LIGAMENT INJURIES ARE EXTREMELY COMMON.
2 IT'S BEEN REPORTED IN THE LITERATURE THAT MORE THAN
3 200,000 ACL INJURIES HAPPEN EACH YEAR JUST IN THE
4 U.S.; WHEREAS, INDUSTRY ESTIMATES -- ACTUALLY
5 INDICATED THERE'S PROBABLY DOUBLE THAT AMOUNT IN
6 REALITY.

7 WITH REGARD TO ROTATOR CUFF TEARS, BASED
8 ON 2010 CENSUS DATA IN AMERICA, THERE'S AT LEAST 5.7
9 MILLION AMERICANS THAT HAVE A ROTATOR CUFF TEAR.
10 DAY AFTER DAY I PERSONALLY SEE THESE PATIENTS. I
11 SEE THE SIGNIFICANT DISABILITY THAT IT CAUSES IN
12 THEIR LIVES, AND I SEE THE DESPERATION ON THEIR
13 FACES WHEN I TELL THEM IT'S GOING TO BE SEVERAL
14 MONTHS BEFORE THEY CAN GET BACK TO AN ACTIVITY THAT
15 THEY ENJOY.

16 THE MILITARY, THIS UNMET NEED IS EVEN MORE
17 SIGNIFICANT. IT'S BEEN ESTIMATED THAT IN THE
18 MILITARY POPULATION IT'S AS MUCH AS TEN TIMES HIGHER
19 TO HAVE AN ACL INJURY COMPARED TO THE GENERAL
20 POPULATION.

21 OTHER STUDIES HAVE EVEN SHOWN THAT AMONG
22 ACTIVE DUTY ARMY PERSONNEL, THE OVERALL RATE OF
23 PERMANENT DISABILITY DISCHARGE RELATED TO ACL IS 10
24 PERCENT. THIS IS A HUGE EXPENSE ON OUR NATIONAL
25 BUDGET.

BARRISTERS' REPORTING SERVICE

1 I'D ALSO LIKE TO SAY THAT ACL TEARS MOST
2 COMMONLY AFFECT YOUNG PATIENTS, PATIENTS UNDER AGE
3 20. UNFORTUNATELY THIS GROUP IS ALSO AT MOST RISK
4 FOR REINJURY. THERE'S A HUGE LINK BETWEEN --
5 THERE'S A CLEAR ASSOCIATION BETWEEN ACL TEARS AND
6 DEVELOPMENT OF OSTEOARTHRITIS. AND AS THIS
7 POPULATION AGES, THIS REPRESENTS A HUGE HEALTHCARE
8 ISSUE FOR OUR COUNTRY. IN FACT, HEALTHCARE
9 RESEARCHERS ESTIMATE BY LONG-TERM COST UTILITY
10 ANALYSIS THAT ANY INNOVATION IN THE TREATMENT OF ACL
11 TEARS WHICH HAS THE ABILITY TO DECREASE THE RELATIVE
12 RISK OF KNEE OSTEOARTHRITIS EVEN BY ONE-FOURTH WOULD
13 SAVE SOCIETY \$460 MILLION EACH YEAR.

14 WITHOUT GETTING INTO TECHNICAL DETAILS,
15 I'D ALSO LIKE TO UNDERSCORE -- OKAY. IN CLOSING,
16 I'D JUST LIKE TO STATE THAT THESE INJURIES ARE A
17 SIGNIFICANT IMPACT ON OUR POPULATION. I HOPE THAT
18 THE BOARD CAN FIND A MECHANISM BY WHICH TO FUND THE
19 STUDY WHICH IS ON THE CUSP OF TIER I. AND I THINK
20 IT WOULD HAVE TREMENDOUS BENEFIT TO OUR PATIENTS.
21 THANKS.

22 MR. LEZAK: HELLO. MY NAME IS JASON
23 LEZAK. I'M HERE FROM THE SAME GRANT PROPOSAL AS
24 DR. KREMEN. I'M A FOUR-TIME OLYMPIC SWIMMER, WON
25 EIGHT MEDALS, FOUR OF THEM GOLD. I'VE BEEN THE TEAM

BARRISTERS' REPORTING SERVICE

1 CAPTAIN IN THE LAST TWO OLYMPICS AND CURRENT WORLD
2 RECORD HOLDER. I WAS LUCKY ENOUGH TO BE ABLE TO WIN
3 AN ESPE AWARD IN 2008.

4 MANY ATHLETES AND PROFESSIONAL AND
5 AMATEURS SPEND THEIR LIVES TRAINING LIKE I DID, AND
6 THEY DO WHATEVER THEY CAN TO ACHIEVE THAT TOP
7 PERFORMANCE. UNFORTUNATELY, INJURIES TEND TO DERAIL
8 THEM. AND I WAS SWIMMING SINCE THE AGE OF FIVE, HAD
9 MY BEST PERFORMANCE AT 32 YEARS OLD, AND AT 36,
10 PRIOR TO THE 2012 GAMES, I HAD ONE OF THOSE INJURIES
11 THAT NEEDED SURGICAL INTERVENTION. I WOUND UP
12 HAVING KNEE SURGERY.

13 I JUST REMEMBER THAT THE RECOVERY PROCESS
14 FROM THAT WAS NOT EXACTLY HOW I HAD HOPED FOR IT TO
15 BE LEADING INTO THE OLYMPICS. I KNOW SOME OF MY
16 TRAINING WAS CHANGED A LITTLE BIT, A LOT OF SWELLING
17 IN MY LEG. I HAD TO TRAVEL A LOT. BEING ON THE
18 AIRPLANES DEFINITELY WAS HARD FOR ME TO GET TO THAT
19 HIGHEST LEVEL THAT I HAD TO HAVE BEEN. I KIND OF
20 THOUGHT BACK THINKING WHAT IF THERE WAS SOMETHING
21 THAT COULD HAVE DONE A LITTLE BIT BETTER. I HAD
22 GREAT DOCTORS, GREAT SURGEONS, BUT UNFORTUNATELY
23 THEY DID THE BEST THEY CAN DO, AND IT WAS GOOD
24 ENOUGH FOR ME TO MAKE THE OLYMPIC TEAM, BUT IT
25 WASN'T TO THE POINT WHERE I WANTED TO BE AND WIN

BARRISTERS' REPORTING SERVICE

1 THAT INDIVIDUAL MEDAL LIKE I'D ALWAYS DREAMED ABOUT.

2 ATHLETES, WE'RE ALWAYS LOOKING TO RECOVER

3 FASTER AND STRONGER. I'M NOT REALLY PERSONALLY

4 FAMILIAR WITH STEM CELLS, BUT I HEAR MANY

5 PROFESSIONAL ATHLETES WHO ARE ALREADY PURSUING

6 SO-CALLED STEM CELLS TREATMENTS BOTH HERE AND

7 ABROAD. YOU HEAR OF SOME OF THESE GREAT PEOPLE

8 GOING TO EUROPE TO TRY DIFFERENT EXPERIMENTAL

9 THINGS, BUT REALLY THERE'S NOT A WHOLE LOT OF

10 RESEARCH BEHIND SOME OF THESE THINGS THEY'RE DOING.

11 I'M NOT AWARE OF ANY OF THESE TREATMENTS THAT ARE

12 BEING FDA APPROVED. SO IT SEEMS TO ME THERE'S A

13 CLEAR NEED FOR FURTHER RESEARCH ON THE USE OF STEM

14 CELLS TO IMPROVE THE HEALING OF SPORTS INJURIES.

15 I THINK WE NEED TO OPTIMIZE THE SAFETY OF

16 THESE TREATMENTS AND SCIENCE BEHIND THEM. IN THIS

17 LIGHT, I STRONGLY SUGGEST THAT YOU GUYS FUND THIS

18 WHICH AIMS AT THE HEALING OF TENDON AND LIGAMENT

19 INJURIES. I THINK THIS TYPE OF RESEARCH PROVIDES A

20 TREMENDOUS OPPORTUNITY TO HAVE A MEANINGFUL IMPACT

21 ON THE LIVES OF NUMEROUS CALIFORNIANS AS WELL AS THE

22 REST OF OUR NATION. THANK YOU.

23 MR. SHEEHY: ADDITIONAL PUBLIC COMMENT

24 EITHER HERE OR ON THE PHONE? THEN MS. BONNEVILLE,

25 COULD YOU CALL THE ROLL.

BARRISTERS' REPORTING SERVICE

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COULD COUNSEL REPEAT THE MOTION?

MR. HARRISON: THE MOTION IS TO APPROVE FUNDING FOR THE TRAN APPLICATIONS IN TIER I EXCEPT TRAN1-08468 AND TRAN1-08522 WHICH ARE DEFERRED.

MR. SHEEHY: ALSO NOT TO FUND THE OTHER --

MR. HARRISON: AND NOT TO FUND THE REMAINING APPLICATIONS.

MR. SHEEHY: AND THE FORM THAT WE SHOULD USE IF WE HAVE CONFLICTS?

MR. HARRISON: YES OR NO EXCEPT WITH RESPECT TO THOSE APPLICATIONS IN WHICH YOU HAVE A CONFLICT.

MR. SHEEHY: THANK YOU.

MS. BONNEVILLE: ANNE-MARIE DULIEGE.

DR. DULIEGE: YES.

MS. BONNEVILLE: DAVID HIGGINS.

DR. HIGGINS: YES.

MS. BONNEVILLE: STEVE JUELSGAARD.

MR. JUELSGAARD: YES.

MS. BONNEVILLE: SHERRY LANSING. KATHY LAPORTE.

MS. LAPORTE: YES.

MS. BONNEVILLE: LAUREN MILLER.

MS. MILLER: YES.

MS. BONNEVILLE: ADRIANA PADILLA.

BARRISTERS' REPORTING SERVICE

1 DR. PADILLA: YES.
2 MS. BONNEVILLE: JOE PANETTA.
3 MR. PANETTA: YES.
4 MS. BONNEVILLE: FRANCISCO PRIETO. ROBERT
5 QUINT.
6 DR. QUINT: NO.
7 MS. BONNEVILLE: AL ROWLETT.
8 MR. ROWLETT: YES.
9 MS. BONNEVILLE: JEFF SHEEHY.
10 MR. SHEEHY: YES, EXCEPT FOR APPLICATIONS
11 WITH WHICH I HAVE CONFLICTS.
12 MS. BONNEVILLE: OS STEWARD.
13 DR. STEWARD: YES, EXCEPT FOR THOSE WITH
14 WHICH I HAVE CONFLICTS.
15 MS. BONNEVILLE: JONATHAN THOMAS.
16 CHAIRMAN THOMAS: YES.
17 MS. BONNEVILLE: ART TORRES.
18 MR. TORRES: AYE.
19 MS. BONNEVILLE: DIANE WINOKUR.
20 MS. WINOKUR: YES.
21 MR. HARRISON: DR. HIGGINS, JUST TO BE
22 CLEAR, IT APPEARS THAT YOU MAY HAVE A CONFLICT WITH
23 RESPECT TO ONE APPLICATION, SO IF YOU WOULD MODIFY
24 YOUR VOTE.
25 DR. HIGGINS: YES, EXCEPT FOR THOSE WITH

BARRISTERS' REPORTING SERVICE

1 WHICH I HAVE CONFLICTS.

2 MR. HARRISON: THANK YOU. MOTION CARRIES.

3 MR. SHEEHY: THANK YOU, MR. HARRISON.

4 THANK YOU, EVERYONE, FOR THE LIVELY DISCUSSION. I'M
5 TURNING IT BACK OVER TO CHAIRMAN THOMAS TO RESUME.

6 CHAIRMAN THOMAS: THANK YOU, MR. SHEEHY.

7 I HAVE ONE MORE ITEM TO CONSIDER BEFORE WE BREAK FOR
8 LUNCH; THAT IS, ITEM 11, CONSIDERATION OF AMENDMENTS
9 TO CONFERENCE GRANT CONCEPT PLAN. DR. THAKAR WILL
10 PRESENT.

11 DR. THAKAR: I'M BACK. RAHUL THAKAR FROM
12 THE CIRM TEAM.

13 MR. CHAIRMAN, MEMBERS OF THE BOARD, FOR
14 YOUR CONSIDERATION, I'D LIKE TO BRING TO YOU A
15 CONCEPT PROPOSAL UPDATE FOR THE CONFERENCE GRANT
16 PROGRAM. IT'S PRETTY STRAIGHTFORWARD, BUT I'LL
17 SUMMARIZE.

18 THERE ARE TWO MODIFICATIONS BEFORE YOU
19 TODAY. THE FIRST IS FOR THE MECHANISM 1, WHICH IS
20 MORE OR LESS THE TRADITIONAL CONFERENCE GRANT.
21 THESE ARE THE GRANTS OR THE APPLICATIONS THAT COME
22 INTO CIRM THAT ARE PROPOSED OR MEETINGS PROPOSED OR
23 MEETINGS INITIATED BY AN APPLICANT. ESSENTIALLY THE
24 APPLICANT'S IDEA FOR A MEETING, THEY COME TO US FOR
25 FUNDING.

BARRISTERS' REPORTING SERVICE

1 WE, THE CIRM TEAM, WOULD LIKE TO PUT A
2 CONTINGENCY ON APPROVED MECHANISM 1 CONFERENCE
3 GRANTS, THAT CIRM BE GIVEN A 30-MINUTE SPEAKING SLOT
4 DURING THE COURSE OF THE MEETING. THE PURPOSE OF
5 THE SPEAKING SLOT IS ESSENTIALLY TO INFORM PEOPLE
6 ABOUT CIRM, CIRM'S MISSION, AND ESSENTIALLY RECRUIT
7 OR HUNT, IS THE TERM WE LIKE TO USE, INTERNALLY FOR
8 GOOD SCIENTIFIC IDEAS, GOOD PROJECTS, AND LET'S FILL
9 UP OUR PIPELINE WITH SOME GREAT IDEAS.

10 THE SECOND MODIFICATION THAT IS REQUESTED
11 BY THE TEAM IS FOR MECHANISM 2. MECHANISM 2 REFERS
12 TO CONFERENCE GRANTS THAT ARE PROPOSED BY CIRM; FOR
13 EXAMPLE, SOMETHING LIKE THE ANNUAL SPARK OR THE
14 ANNUAL BRIDGES MEETING, FOR EXAMPLE. WHAT CIRM IS
15 REQUESTING BE MODIFIED FOR THAT MECHANISM IS, ONE,
16 HONORARIA BE PROVIDED. IT'S AN ALLOWABLE COST FOR
17 INVITED SPEAKERS. THE SECOND, UP TO 10-PERCENT
18 SALARY SUPPORT FOR THE PROGRAM DIRECTOR'S TIME SPENT
19 CONDUCTING CONFERENCE-SPECIFIC ACTIVITIES. AND
20 FINALLY, THE THIRD ITEM FOR REQUESTED MODIFICATION,
21 REASONABLE SALARY SUPPORT FOR THE ADMINISTRATIVE
22 STAFF TIME CONDUCTING CONFERENCE-SPECIFIC ACTIVITIES
23 BE INCLUDED.

24 AND SO THE CIRM TEAM RECOMMENDATION IS AS
25 FOLLOWS: THE CIRM TEAM REQUESTS THAT THE ICOC

BARRISTERS' REPORTING SERVICE

1 APPROVE THESE MODIFICATIONS TO THE CONCEPT PROPOSAL
2 FOR THE CONFERENCE GRANT PROGRAM. THANK YOU.

3 CHAIRMAN THOMAS: DO I HEAR A MOTION TO
4 THAT EFFECT?

5 DR. LUBIN: SO MOVED.

6 MS. WINOKUR: SECOND.

7 CHAIRMAN THOMAS: MOVED BY DR. LUBIN,
8 SECONDED BY MS. WINOKUR. BOARD DISCUSSION? HEARING
9 NONE, ANY PUBLIC COMMENT ON THIS PARTICULAR ITEM?
10 MR. HARRISON, CAN THIS BE DONE BY VOICE VOTE?

11 MR. HARRISON: YES, EXCEPT WITH RESPECT TO
12 ON THE PHONE.

13 CHAIRMAN THOMAS: ALL THOSE IN FAVOR
14 PLEASE SAY AYE. OPPOSED? ANY ABSTENTIONS? MARIA,
15 PLEASE CALL THE ROLL FOR THOSE ON THE PHONE.

16 MS. BONNEVILLE: JACK DIXON. AL ROWLETT.

17 MR. ROWLETT: YES.

18 MS. BONNEVILLE: CARL WARE.

19 DR. WARE: YES.

20 CHAIRMAN THOMAS: OKAY. MR. HARRISON, I
21 THINK I CAN SAFELY SAY THAT WAS APPROVED. OKAY. SO
22 WE ARE NOW GOING TO BREAK FOR LUNCH AND CLOSED
23 SESSION. MR. HARRISON, COULD YOU REGALE US WITH THE
24 APPROPRIATE SUB, SUB, SUBSECTION RECITATION?

25 MR. HARRISON: I CAN. THE BOARD WILL BE

BARRISTERS' REPORTING SERVICE

1 CONVENING IN CLOSED SESSION TO DISCUSS PERSONNEL
2 PURSUANT TO GOVERNMENT CODE SECTION 11126
3 SUBDIVISION A AND HEALTH AND SAFETY CODE SECTION
4 125290.30(F)(3)(D).

5 CHAIRMAN THOMAS: SO WE WILL CONVENE,
6 MARIA, WHERE IS THAT GOING TO BE?

7 MS. BONNEVILLE: CLOSED SESSION IS IN THE
8 ROOM WHERE BREAKFAST WAS THIS MORNING. LUNCH IS
9 DIRECTLY OUTSIDE THAT ROOM IN THE HALLWAY. SO GRAB
10 YOUR LUNCH AND PLEASE COME INTO THAT ROOM. FOR
11 THOSE OF YOU ON THE PHONE, WE SENT YOU THE CLOSED
12 SESSION DIAL-IN. IF YOU NEED IT RESENT, PLEASE JUST
13 LET ME KNOW.

14 CHAIRMAN THOMAS: THANK YOU. SO WE ARE
15 TEMPORARILY ADJOURNED UNTIL AFTER CLOSED SESSION.

16 (A RECESS WAS TAKEN.)

17 (A CLOSED SESSION WAS THEN HAD, NOT
18 REPORTED NOR HEREIN TRANSCRIBED. THE FOLLOWING WAS
19 THEN HEARD IN OPEN SESSION:)

20 CHAIRMAN THOMAS: LADIES AND GENTLEMEN, IF
21 YOU WOULD PLEASE TAKE YOUR SEATS. OKAY. THOSE OF
22 YOU ON THE PHONE, WE'RE READY TO RECONVENE HERE.
23 WE'RE NOW INTO THE DISCUSSION ITEM SEGMENT OF THE
24 AGENDA. ITEM 14, FINANCIAL AUDIT RESULTS FROM THE
25 MACIAS FIRM. MR. HARNER, YOU READY TO GO?

BARRISTERS' REPORTING SERVICE

1 TO, AS I JUST SAID TO ART, TO QUOTE THE
2 LATE HARRY VON ZELL IN A SPOONERISM OF NOTE, "LADIES
3 AND GENTLEMEN OF THE AUDIO RADIANCE, ARE YOU ON THE
4 LINE NOW?" AL, ARE YOU THERE? ANYBODY ON THE LINE?
5 PEOPLE ARE LISTENING. OKAY. VERY GOOD. MR.
6 HARNER.

7 MR. HARNER: THANK YOU. AFTERNOON,
8 MEMBERS OF THE COMMITTEE. MY NAME IS CRAIG HARNER.
9 I'M AN AUDIT MANAGER WITH MACIAS, GINI & O'CONNELL.
10 I WAS THE AUDIT MANAGER IN CHARGE OF THE CIRM
11 ENGAGEMENT FOR THE YEAR ENDED JUNE 30, 2015.

12 BEFORE I GET TO MY PRESENTATION, I JUST
13 WANT TO THANK THE COMMITTEE FOR THE OPPORTUNITY TO
14 PRESENT THE RESULTS OF OUR WORK. I ALSO WANT TO
15 THANK MANAGEMENT AND STAFF OF CIRM FOR ALL THEIR
16 ASSISTANCE AND SUPPORT DURING THE AUDIT.

17 SO I'M HERE TO PRESENT THE RESULTS OF OUR
18 WORK. WE WERE ENGAGED TO PERFORM AN AUDIT OF CIRM'S
19 FINANCIAL STATEMENTS FOR THE FISCAL YEAR ENDED JUNE
20 30, 2015, AND TO EXPRESS AN OPINION ON THE FINANCIAL
21 STATEMENTS FOR THE YEAR THEN ENDED.

22 WHEN I SAY EXPRESS AN OPINION, WHAT I'M
23 TALKING ABOUT IS WE ARE PROVIDING REASONABLE
24 ASSURANCE THAT THE FINANCIAL STATEMENTS ARE FREE OF
25 WHAT'S CALLED MATERIAL MISSTATEMENT WHETHER DUE TO

BARRISTERS' REPORTING SERVICE

1 ERRORS OR FRAUD. WHEN I SAY REASONABLE ASSURANCE,
2 THIS CONCEPT MEANS THAT WE DON'T GIVE A HUNDRED
3 PERCENT ASSURANCE, MEANING WE DON'T TEST OR LOOK AT
4 100 PERCENT OF THE TRANSACTIONS, BUT WE STILL
5 PROVIDE A VERY HIGH DEGREE OF ASSURANCE.

6 AND SO WE'VE ISSUED OUR INDEPENDENT
7 AUDITOR'S REPORT, WHICH YOU'LL FIND ON PAGE 3 OF THE
8 FINANCIAL STATEMENTS. WE ISSUED IT ON OCTOBER 15,
9 2015, AND WE ISSUED WHAT'S CALLED AN UNMODIFIED
10 OPINION. AN UNMODIFIED OPINION IS THE HIGHEST LEVEL
11 OF ASSURANCE THAT AN INDEPENDENT AUDITOR CAN GIVE AN
12 ENTITY REGARDING THEIR FINANCIAL STATEMENTS.

13 ONE OTHER ITEM TO NOTE HERE IS THAT WE
14 PERFORMED OUR AUDIT IN ACCORDANCE WITH THE
15 GOVERNMENT AUDITING STANDARDS WHICH ALSO REQUIRES US
16 TO REPORT TO THE COMMITTEE ANY INTERNAL CONTROL
17 DEFICIENCIES THAT RISE TO THE LEVEL OF WHAT WE CALL
18 A SIGNIFICANT DEFICIENCY OR A MATERIAL
19 MISSTATEMENT -- EXCUSE ME -- A MATERIAL WEAKNESS IN
20 INTERNAL CONTROLS. AND WE HAVE PROVIDED THAT ON
21 PAGE 24-25 IN OUR REPORT. AND WE'RE HAPPY TO REPORT
22 THAT WE DID NOT IDENTIFY ANY DEFICIENCIES ON
23 CONTROLS THAT RISE TO THOSE LEVELS.

24 FURTHER, IN THAT REPORT YOU WILL FIND THAT
25 WE'RE ALSO REQUIRED TO REPORT ANY NONCOMPLIANCE WITH

BARRISTERS' REPORTING SERVICE

1 LAWS, REGULATIONS, GRANT AGREEMENTS, CONTRACTS, OR
2 BOND OFFICIAL STATEMENTS. WE ALSO ARE REPORTING
3 THAT WE DID NOT NOTE ANY NONCOMPLIANCE WITH THOSE
4 THAT WOULD AFFECT THE FINANCIAL STATEMENTS.

5 AND THEN, FINALLY, OUR LAST REPORT WAS
6 CALLED THE REQUIRED COMMUNICATIONS. AT THE END OF
7 EACH AUDIT, WE ARE REQUIRED TO PROVIDE THE BOARD OR
8 THOSE CHARGED WITH GOVERNANCE A REPORT OF ANY
9 SIGNIFICANT AUDIT FINDINGS, AND THEN ALSO ANY ITEMS
10 SUCH AS DISAGREEMENTS WITH MANAGEMENT OR JUST
11 INSTANCES THAT OCCURRED DURING THE AUDIT. WE'RE
12 HAPPY TO REPORT THAT EVERYTHING IN THERE WAS NOTHING
13 REALLY OUT OF THE ORDINARY. EVERYTHING WAS FINE.

14 AND AT THIS MOMENT I'LL TAKE ANY
15 QUESTIONS.

16 CHAIRMAN THOMAS: ANY QUESTIONS FOR MR.
17 HARNER?

18 MS. LAPORTE: JUST ONE. COULD YOU JUST
19 REALLY BRIEFLY DESCRIBE WHAT PROCEDURES DO YOU USE
20 TO ASSESS THE POSSIBILITY OF FRAUD? WHAT SORTS OF
21 ISSUES DO YOU LOOK AT?

22 MR. HARNER: SURE. WE DO A NUMBER OF
23 PROCEDURES. THE FIRST THING IS OUR WHOLE ENGAGEMENT
24 TEAM GETS TOGETHER BEFORE THE AUDIT STARTS, AND
25 WE'LL START LOOKING AT NEWS ARTICLES OR WE'LL START

BARRISTERS' REPORTING SERVICE

1 LOOKING AT PRIOR YEAR FINANCIAL STATEMENTS, AND
2 WE'LL START LOOKING IN WHICH AREAS OF THE FINANCIAL
3 STATEMENTS WOULD BE MORE LIKELY TO HAVE A RISK OF
4 FRAUD. IN THIS CASE WE LOOKED CONSIDERABLY AT THE
5 GRANT EXPENDITURES. WE LOOK AT A LOT OF PROCEDURES
6 THERE.

7 ALSO, DURING OUR AUDIT WE ARE ALSO
8 REQUIRED BY OUR PROFESSIONAL AUDITING STANDARDS TO
9 MEET WITH KEY INDIVIDUALS IN THE ORGANIZATION AND
10 HAVE A ONE-ON-ONE MEETING WITH THEM TO DISCUSS ANY
11 SUSPECTED FRAUD, ALLEGATIONS OF FRAUD, OR ANY AREAS
12 IN THE FINANCIAL STATEMENTS WHERE THEY THINK FRAUD
13 IS MORE LIKELY TO OCCUR. AND THEN WE INCORPORATE
14 ANYTHING THAT COMES THAT HEIGHTENS OUR RISK
15 ASSESSMENTS. WE PERFORM PROCEDURES TO ADDRESS
16 THOSE, SUCH AS MAYBE FURTHER TESTING OR EXPANDING
17 THE SCOPE OF OUR SAMPLES.

18 CHAIRMAN THOMAS: ANY OTHER COMMENTS OR
19 QUESTIONS OF MR. HARNER?

20 DR. STEWARD: I HAVE A QUESTION. THIS IS
21 NOT SPECIFIC TO THE AUDIT REPORT, BUT I'M JUST
22 CURIOUS. AND I DON'T KNOW THE RULES ON THIS. I
23 KNOW IN AT LEAST SOME OTHER SITUATIONS THERE'S A
24 CHANGE OF THE AUDIT GROUP ON A PERIODIC BASIS. IS
25 THAT SOMETHING THAT'S DONE HERE, OR ARE YOU GUYS THE

BARRISTERS' REPORTING SERVICE

1 ONES --

2 MR. HARNER: AS FAR AS I KNOW. I BELIEVE
3 IN CALIFORNIA THEY JUST STARTED THIS WHERE THEY'RE
4 REQUIRING NOT NECESSARILY THE AUDIT GROUP OR FIRM,
5 BUT THE PARTNER WHO'S IN CHARGE OF THE ENGAGEMENT.
6 I DON'T KNOW THE EXACT YEAR, BUT I BELIEVE IT'S
7 EVERY FIVE YEARS THEY WANT THAT PERSON TO BE ROTATED
8 OFF.

9 DR. STEWARD: OKAY. WHERE ARE WE IN THAT
10 PROCESS?

11 MR. HARNER: WE HAVE BEEN THE AUDITOR, I
12 BELIEVE, SINCE 2006, 2007. SO WE PROBABLY ARE GOING
13 TO HAVE TO START LOOKING AT THAT.

14 MS. SILVA-MARTIN: I CAN SPEAK TO THAT.
15 SO WE ENGAGED -- SO THE FIRST COUPLE OF YEARS, I
16 BELIEVE, WE HAD A DIFFERENT AUDIT GROUP PERFORM THE
17 AUDIT, AND WE DID A COMPETITIVE BID. AND MACIAS WON
18 THE CONTRACT. AND THEN I BELIEVE IT WAS TWO OR
19 THREE YEARS AGO, I'M NOT EXACTLY SURE WHICH, WE WENT
20 OUT FOR ANOTHER COMPETITIVE BID AND THEY WERE AGAIN
21 THE AUDIT TEAM THAT WAS SELECTED. BUT WE WILL
22 CONTINUE TO DO THAT PER THE CONTRACT REQUIREMENTS.

23 CHAIRMAN THOMAS: OTHER QUESTIONS? WITH
24 THAT, THANK YOU, MR. HARNER. AND I WOULD NOTE THAT
25 THIS IS FURTHER SPEAKING TO THE WONDERFUL JOB THAT

BARRISTERS' REPORTING SERVICE

1 CHILA AND HER TEAM DO IN KEEPING OUR FINANCIAL
2 MATTERS IN ORDER. SO, CHILA, THANK YOU.

3 MS. SILVA-MARTIN: THANK YOU. I WOULD
4 LIKE TO SAY SOMETHING. SO IT REALLY TAKES A LOT OF
5 DIFFERENT TEAMS AT CIRM TO MAKE SURE THAT WE HAVE A
6 CLEAN AUDIT. IT STARTS WITH OUR PROCUREMENT AND
7 CONTRACT TEAM AS WELL AS OUR FINANCE TEAM. BUT A
8 COUPLE OF TEAMS THAT I DON'T THINK GET RECOGNIZED
9 FOR ALL OF THEIR EFFORTS ARE OUR I.T. TEAM AND GABE
10 THOMPSON AND HIS TEAM.

11 SO WE TALKED ABOUT THE BIGGEST AMOUNT OF
12 MONEY THAT GOES OUT IS OUR GRANT PAYMENTS. AND
13 EVERY MONTH WE PROBABLY PROCESS ABOUT A HUNDRED
14 GRANT PAYMENTS, AND WE WORK VERY CLOSELY WITH GABE'S
15 TEAM TO MAKE SURE THAT THOSE ARE ACCURATE BEFORE WE
16 SEND THEM TO THE DEPARTMENT OF GENERAL SERVICES.
17 AND, OF COURSE, THE I.T. TEAM HAS BEEN RESPONSIBLE
18 FOR PUTTING TOGETHER A GRANTS MANAGEMENT SYSTEM
19 THAT'S REALLY MADE THAT PROCESS WORK REALLY WELL FOR
20 YOU. SO WE'RE REALLY APPRECIATIVE OF ALL OF THEIR
21 EFFORTS IN MAKING THOSE PAYMENTS HAPPEN QUICKLY AND
22 WITHOUT ANY ISSUES. SO THANK YOU.

23 CHAIRMAN THOMAS: THANK YOU. THAT'S
24 IMPORTANT POINTS TO NOTE. THANK YOU VERY MUCH.
25 THANK YOU, MR. HARNER, FOR YOUR WORK.

BARRISTERS' REPORTING SERVICE

1 BECAUSE WE WANTED TO KEEP THE ABSOLUTELY
2 MOST INTERESTING THING ON THE AGENDA TILL LAST,
3 WHICH IS MR. HARRISON'S UPDATE ON THE CONFLICT OF
4 INTEREST LAWS, WE'RE GOING TO SWITCH ORDER HERE AND
5 GO TO DR. DOYLE AND CREASEY FOR AN UPDATE ON OUR
6 CIRM CLINICAL STAGE PROJECTS.

7 DR. DOYLE: MR. CHAIRMAN, BOARD MEMBERS,
8 THANKS VERY MUCH FOR LETTING US GO SECOND TO LAST
9 THIS TIME AS OPPOSED TO LAST. SO WHAT WE'RE GOING
10 TO TRY TO DO AT EVERY IN-PERSON MEETING IS TO
11 PRESENT AN UPDATE, VERY BRIEF, ON SOME THINGS THAT
12 ARE IN OUR CLINICAL PORTFOLIO. AND THIS IS A BIT OF
13 AN EXPERIMENT. IT'S HERE TO HELP CONNECT YOU WITH
14 THE WORK THAT WE'RE DOING. BUT IF THERE'S ANYTHING
15 THAT WE CAN DO DIFFERENTLY OR BETTER OR SUGGESTIONS
16 FOR ANY OF THESE PRESENTATIONS, WE'D BE HAPPY TO
17 TAKE THEM.

18 I ALSO WANT TO JUST GIVE IN FULL
19 DISCLOSURE, I AM NOT AN EYE SPECIALIST. I KNOW THAT
20 WE HAVE ONE ON THE BOARD. I'M A LITTLE NERVOUS
21 ABOUT TALKING ABOUT THE EYE AS A PULMONOLOGIST, BUT
22 I DO ALSO WANT TO ALSO LET THE BOARD KNOW THAT THE
23 NEXT TIME THAT THE WORD "PULMONARY" APPEARS ON A
24 SLIDE, IT WILL BE SPELLED CORRECTLY, FOR THOSE OF
25 YOU WHO NOTICED.

BARRISTERS' REPORTING SERVICE

1 EYE DISEASES AND VISUAL IMPAIRMENT IS
2 REALLY A MAJOR PUBLIC HEALTH PROBLEM. IN THIS
3 COUNTRY ALONE UP TO \$250 BILLION ARE SPENT. AS A
4 PUBLIC HEALTH PROBLEM, THERE ARE A COUPLE OF THINGS
5 TO CONSIDER. FIRST OF ALL, AS WE AGE, AND WE DO
6 HAVE AN AGING POPULATION, AGE-RELATED EYE DISEASES
7 ARE BECOMING MORE COMMON, MORE PROBLEMATIC.
8 SECONDLY, THERE ARE EYE DISEASES WHICH AFFECT
9 MINORITY POPULATIONS DISPROPORTIONATELY, INCLUDING
10 GLAUCOMA IN AFRICAN-AMERICANS. AND THIRDLY, A LOT
11 OF EYE DISEASES ARE ASSOCIATED WITH COMORBID
12 CONDITIONS SUCH AS DIABETES. AS WE HAVE MORE FOLKS
13 LIVING WITH THESE CONDITIONS, WE'RE GOING TO SEE
14 MORE OF A PROBLEM.

15 FOLKS WHO ARE AT RISK FOR BLINDNESS, THERE
16 ARE PEOPLE WITH GENETIC INHERITED EYE DISEASES, BUT
17 THERE ARE ALSO, AS I MENTIONED, EYE DISEASES THAT
18 ARE ACQUIRED AS WE LIVE LONGER. PATIENTS WITH
19 DIABETES I MENTIONED, ALSO STROKE VICTIMS, FOLKS WHO
20 HAVE EYE SURGERY. ACTUALLY THERE'S A FAIR INCIDENCE
21 OF PEOPLE WHO WORK WITH OR NEAR SHARP OBJECTS OR
22 TOXIC CHEMICALS WHO HAVE EYE INJURY. IN THIS
23 COUNTRY FREQUENTLY THESE CAN BE REPAIRED WITH
24 CORNEAL TRANSPLANTS; BUT IN THE REST OF THE WORLD
25 WHERE THAT'S NOT AVAILABLE, THIS CAN BE A VERY

BARRISTERS' REPORTING SERVICE

1 SIGNIFICANT GROUP OF FOLKS.

2 AND, FINALLY, THERE IS A RETINOPATHY OF
3 PREMATURE BABIES WHICH, AS WE'VE BECOME MORE
4 SUCCESSFUL IN KEEPING YOUNGER AND YOUNGER CHILDREN
5 ALIVE, WE ARE SEEING MORE OF THIS.

6 SO THIS IS ABOUT AS FAR AS I'M GOING TO GO
7 ON THE ANATOMY OF THE EYE. WHAT I'M GOING TO SAY IS
8 THAT THE PROJECTS THAT WE'RE DOING HERE AT CIRM
9 FOCUS ON THE BACK OF THE EYE, PRIMARILY ON THE
10 RETINA, WHICH IS REALLY THE NERVE PART OF THE EYE.
11 A LOT OF THE PROBLEMS, PARTICULARLY THE SCARS AND
12 THINGS THAT CHILDREN OR OTHERS MIGHT EXPERIENCE FROM
13 INJURY, ARE IN THE FRONT OF THE EYE AND TYPICALLY
14 CAN BE DEALT WITH WITH CORNEAL TRANSPLANTS AND/OR
15 LENS IMPLANTS, WHICH MAYBE SOME OF US HERE TODAY
16 MIGHT EVEN HAVE.

17 SO UNMET MEDICAL NEEDS IN EYE DISEASE IN
18 TERMS THAT WE CAN SORT OF PUT THE THINGS THAT WE'RE
19 DOING ARE THERE'S GENETIC DISEASES, AND I'VE GOT A
20 LIST OF THEM HERE. AND ONE OF THE ONES HIGHLIGHTED
21 IS RETINITIS PIGMENTOSA. AND I'M GOING TO TALK
22 ABOUT THE PROJECTS -- OR I'M GOING TO HAVE MY
23 COLLEAGUE ABLA CREASEY SPEAK TO THOSE PROJECTS. AND
24 WE ALSO HAVE ACQUIRED DISEASES OF THE EYE. AND ONE
25 OF THE MAJOR ISSUES IN THIS COUNTRY AT THE MOMENT IS

BARRISTERS' REPORTING SERVICE

1 AGE-RELATED MACULAR DEGENERATION.

2 SO LET ME JUST SPEAK A LITTLE BIT ABOUT
3 AGE-RELATED MACULAR DEGENERATION. IN THE TOP YOU
4 WILL SEE A PICTURE OF WHAT SOMEONE WITH FAIRLY
5 ADVANCED AGE-RELATED MACULAR DEGENERATION MIGHT
6 EXPERIENCE, AND THAT IS A LOSS OF CENTRAL VISION.
7 AND THAT IS THE CHARACTERISTIC OF AMD. YOU CAN SEE
8 ON THE EYE CHART A SIMILAR IMAGE WHERE THE CENTRAL
9 PART OF THAT CHART IS NOT ABLE TO BE READ BY THE
10 PATIENT. THIS IS A LEADING CAUSE OF BLINDNESS IN
11 PATIENTS OVER 55 YEARS OF AGE, AND IT IS, AGAIN,
12 CHARACTERIZED BY PROGRESSIVE LOSS OF CENTRAL VISION.

13 THE LOSS OF VISION IS DUE TO SOMETHING
14 WHICH I'M AFRAID WE CAN'T QUITE SEE ON HERE, BUT THE
15 RETINAL PIGMENT EPITHELIUM IS A VERY IMPORTANT PART
16 OF THE EYE THAT PROVIDES NUTRITION AND SUPPORT FOR
17 THE RODS AND CONES OF THE PHOTORECEPTORS. AND IT'S
18 THE DYSFUNCTION AND LOSS OF THE RPE WHICH LEADS TO
19 THE PROBLEMS WITH AMD.

20 AND JUST TO TAKE A QUICK LOOK AT SOME
21 FUNDOSCOPIC EXAMS, ON THE FAR LEFT IS A NORMAL
22 FUNDOSCOPIC EXAM. YOU MIGHT HAVE EXPERIENCED THIS
23 WHEN YOU YOURSELF HAVE HAD YOUR EYES CHECKED AND YOU
24 SEE THAT PHOTONEGATIVE IMAGE OF SOME BLOOD VESSELS
25 AND A BRIGHT SPOT AND YOU WONDER WHAT YOU'RE SEEING.

BARRISTERS' REPORTING SERVICE

1 AND THAT'S FROM THE ACTUAL BACK OF THE EYE OR THE
2 RETINA, WHICH IS THE PART WE'RE TALKING ABOUT.

3 IN A NORMAL EXAM, YOU CAN SEE VESSELS
4 COMING OUT FROM AROUND THE BRIGHT SPOT THERE, THE
5 OPTIC DISK, AND A SORT OF NORMAL VASCULATURE. IN
6 EARLY AMD, WHEN YOU HAVE DYSFUNCTION OF THE RPE,
7 WHICH I MENTIONED, YOU GET THESE SPOTS. I DON'T
8 THINK THEY'RE VERY EASY TO SEE HERE. YOU GET
9 DEGENERATION OF A MEMBRANE THAT SITS UNDER THE RPE
10 CALLED BRUCH'S MEMBRANE, WHICH IS ACTUALLY FIVE
11 LAYERS OF CELLS. AND YOU GET ACCUMULATION OF THESE
12 FATTY DEPOSITS CALLED DRUSEN. NOW, DRUSEN ARE
13 ACTUALLY A SIGN OF THE AGING EYE, AND THEY DO SEEM
14 TO INDICATE AN INCREASED RISK FOR AMD.

15 NOW, WHEN YOU BECOME MORE ADVANCED WITH
16 AMD, THERE'S TWO BASIC TYPES. ONE IS DRY ATROPHIC
17 OR GEOGRAPHIC AMD, WHICH IS THE MAJORITY OF PATIENTS
18 WITH ADVANCED AMD. AND UNFORTUNATELY THE TREATMENTS
19 FOR THIS ARE VERY LIMITED RIGHT NOW. A SMALLER
20 GROUP OF PATIENTS MAY PROGRESS OR THEY HAVE WET AMD,
21 AND THIS IS WHERE YOU GET PROLIFERATION OF BLOOD
22 VESSELS IN THE BACK OF THE EYE, AND SOME OF THEM
23 ACTUALLY LEAK BLOOD AND YOU HAVE THE IMAGE THAT YOU
24 SEE HERE. OF COURSE, YOU CAN SEE HOW THIS LEADS TO
25 VISION LOSS.

BARRISTERS' REPORTING SERVICE

1 NOW, THERE'S A SIGNIFICANT BREAKTHROUGH IN
2 WET AMD. IN THE PAST MOST PATIENTS HAD LASER
3 THERAPY SIMPLY TO TAKE CARE OF THIS PROLIFERATION OF
4 VESSELS. THERE'S BEEN ADVANCES IN ANTI-VEGF
5 COMPOUNDS WHICH ARE DIRECTLY INJECTED INTO THE EYE
6 THAT SEEM TO ALSO HELP THIS IN A WAY THAT HAD NEVER
7 BEEN SEEN WITH PHOTOTHERAPIES.

8 I WANT TO TALK AGAIN BRIEFLY ABOUT
9 RETINITIS PIGMENTOSA. AND HERE AGAIN YOU SEE AN
10 IMAGE OF TWO LITTLE BOYS WITH THE BALL IN THE TOP,
11 AND THEN YOU SEE THAT IMAGE FROM THE PERSPECTIVE OF
12 SOMEONE WITH ADVANCED RETINITIS PIGMENTOSA. NOW,
13 RETINITIS PIGMENTOSA IS NOT ONE DISEASE. IT'S
14 ACTUALLY A GROUP OF INHERITED DISEASES THAT CAUSE
15 RETINAL DEGENERATION. PEOPLE WITH RETINITIS
16 PIGMENTOSA EXPERIENCE A GRADUAL DECLINE IN VISUAL
17 LOSS AS THE PHOTORECEPTORS, THE RODS AND CONES WHICH
18 ARE SUPPORTED BY THE RPE, DIE. IT STARTS IN THE
19 PERIPHERAL, ON THE OUTSIDE PART OF THE EYE, AND YOU
20 CAN SEE IN THE EYE CHART OVER THE FAR RIGHT ON THE
21 TOP, THAT'S A NORMAL VISUAL FIELD. YOU CAN ALMOST
22 GET ALL THE WAY AROUND THAT CIRCLE. AND THEN IN THE
23 BOTTOM, YOU CAN SEE THAT IT'S MUCH, MUCH SMALLER.

24 RP CAN BE INHERITED, BUT IT'S ALSO IN 40
25 TO 50 PERCENT OF THE FOLKS WHO HAVE IT AND YOU DON'T

BARRISTERS' REPORTING SERVICE

1 HAVE A FAMILY MEMBER WHO ACTUALLY IS AFFECTED.

2 WHAT'S REALLY KIND OF NEAT ABOUT THE
3 PORTFOLIO THAT WE HAVE RIGHT NOW IS WE HAVE
4 FUNDAMENTALLY THREE SHOTS ON GOAL WITH THREE VERY
5 DIFFERENT APPROACHES TO USING STEM CELLS IN THE EYE.
6 I THINK THAT'S WHAT MAKES US REALLY SORT OF ON THE
7 CUTTING EDGE OF SOME OF THE NEW THERAPIES FOR THESE
8 EYE DISEASES. BASICALLY THE STRATEGIES INCLUDE
9 ACTUALLY REPLACING THE CELLS THAT ARE DEAD OR GONE
10 OR SUPPORTING THE CELLS AS THEY DIE OR DEGENERATE
11 WITH NEUROPROTECTIVE THERAPY. OF COURSE, THERE ARE
12 EYE DISEASES THAT ARE TREATED WITH GENE THERAPY IF
13 YOU HAVE A MONOGENIC DISEASE WHERE GENE CORRECTION
14 WOULD WORK.

15 SO WE'RE REALLY PLEASED THAT -- I DON'T
16 THINK THERE'S A BETTER PORTFOLIO, IF YOU WILL, OF
17 EYE DISEASES THERAPIES RIGHT NOW OUT THERE THAN THE
18 ONE THAT CIRM IS SUPPORTING.

19 SO IN THE INTEREST OF TIME, I'M GOING TO
20 MOVE ALONG AND I'M GOING TO TURN THIS OVER TO MY
21 COLLEAGUE DR. ABLA CREASEY WHO'S ONLY RECENTLY
22 JOINED US AT CIRM AFTER A VERY LONG AND ILLUSTRIOUS
23 CAREER IN BIOTECH. AND SHE'S GOING TO WALK YOU
24 THROUGH THE SPECIFICS OF THE PROGRAMS THAT WE
25 SUPPORT. THANK YOU.

BARRISTERS' REPORTING SERVICE

1 DR. CREASEY: THANK YOU, RAMONA, AND THANK
2 YOU, THE BOARD, FOR HAVING ME. I'VE ONLY BEEN HERE
3 SEVEN WEEKS. SO I'M GETTING MY FEET WET WITH THE
4 OCULAR PROGRAM AT CIRM. I'M DELIGHTED TO BE PART OF
5 IT.

6 SO I'M NOT SURE EVEN IF YOU CAN READ THAT
7 SLIDE, BUT LET ME GUIDE YOU THROUGH IT. IT'S AN EYE
8 CHART. THERE ARE THREE ACTIVE PROGRAMS ON
9 OPHTHALMOLOGY WITHIN CIRM. ONE OF THEM DEALS WITH
10 COMBINING CELLS WITH A SCAFFOLD AND INSERTED IN THE
11 BACK OF THE EYE, AND THAT'S FOR AGE-RELATED MACULAR
12 DEGENERATION. AND THIS IS BEING DONE AT USC BY DR.
13 HUMAYAN.

14 THE SECOND PROGRAM IS IN RETINITIS
15 PIGMENTOSA, AND ACTUALLY THEY TREAT THE PATIENTS
16 WITH ALLOGENEIC CELLS RIGHT IN THE WHITE PART OF THE
17 EYE.

18 AND THE THIRD PROGRAM IS ALSO IN RETINITIS
19 PIGMENTOSA. AND IN THIS SETTING THEY ALSO USE
20 ALLOGENEIC CELLS, BUT THEY TREAT THEM SUBRETINALLY.
21 THAT MEANS IN THE BACK OF THE RETINA. SO I WANT TO
22 TELL YOU A LITTLE MORE DETAIL ABOUT THOSE THREE
23 PROGRAMS.

24 SO THE STUDIES THAT ARE BEING DONE BY
25 DR. HUMAYAN -- BY THE WAY, I'M NOT SURE IF YOU ALL

BARRISTERS' REPORTING SERVICE

1 KNOW THAT DR. HUMAYAN WAS THE RECIPIENT OF THE
2 NATIONAL MEDAL OF AWARD OF TECHNOLOGY AND INNOVATION
3 BY PRESIDENT OBAMA IN DECEMBER OF 2015. SO WE HAVE
4 A DISTINGUISHED INVESTIGATOR AS PART OF THE CIRM
5 COMMUNITY. HE HAS ACTUALLY COME UP WITH A VERY
6 INNOVATIVE TECHNOLOGY WHICH IS COMBINING CELLS WITH
7 A SCAFFOLD THAT IS IMPLANTED SUBRETINALLY IN THOSE
8 PATIENTS. AND THE RATIONALE FOR THAT IS THAT THESE
9 CELLS WILL FUNCTION BECAUSE THE CELLS THAT ARE IN
10 THE BACK OF EYE IN THESE PATIENTS ARE NOT HEALTHY
11 WHILE THESE CELLS ARE HEALTHY, AND THE PATIENTS WILL
12 BE ABLE TO SEE. AGAIN, THE CLINICAL INDICATION IS
13 SEVERE DRY AMD.

14 SO HERE IS A CARTOON OF WHAT THAT MEANS.
15 THEY LAY DOWN THESE RETINAL PIGMENTED EPITHELIAL
16 CELLS ON A SCAFFOLD, AND YOU CAN SEE THE SIZE OF THE
17 SCAFFOLD IS QUITE SMALL. AND THEN THEY'RE INSERTED.
18 AND NOW BEAR WITH ME. I'M GOING TO SHOW YOU HOW
19 THEY DO THAT. SO HERE'S THE CARTOON OF THE EYEBALL.
20 THEY CREATE AN INCISION. THEN THEY ADD -- THIS
21 DIAGRAM SHOWS THE CYLINDER WITH CELLS AND SCAFFOLD
22 THAT'S INSERTED INTO THE INCISION. THEY REMOVE SOME
23 OF THE VITREOUS HUMOR, WHICH IS THAT WHITE PART OF
24 THE EYE, TO MAKE SPACE. THEY INJECT SOME LIQUID TO
25 SEPARATE THE RETINA FROM THE RETINAL -- THE BACK OF

BARRISTERS' REPORTING SERVICE

1 THE EYE. THEY MAKE ANOTHER INCISION INTO THE
2 RETINA. THEN THEY INSERT THE SCAFFOLD WITH THE
3 CELLS. THERE'S A HUNDRED THOUSAND CELLS ON THAT
4 SCAFFOLD. AND THEN THEY REATTACH THE RETINA. AND
5 THE WHOLE PROCEDURE TAKES ONLY MINUTES. SO THAT'S
6 AN AMAZING TECHNOLOGY THAT WE HOPE WILL LEAD TO,
7 AGAIN, RENEWING SIGHT IN THESE PATIENTS.

8 THE SECOND INVESTIGATOR IS DR. HENRY
9 KLASSEN, AND HE'S FROM UC IRVINE. HE'S NOT USING A
10 SCAFFOLD. HE'S MAINLY USING CELLS. BY THE WAY,
11 DR. HUMAYAN AND DR. KLASSEN, THEY HAVE ALREADY FDA
12 APPROVAL, AND THEY ARE IN CLINICAL TRIALS ENROLLING
13 PATIENTS. SO WE'RE EXCITED ABOUT THAT.

14 THE APPROACH THAT DR. KLASSEN USES AND HIS
15 STAFF IS, AGAIN, MAINLY INTRAVITREAL INJECTION OF
16 THE CELLS IN RETINITIS PIGMENTOSA PATIENTS. AND THE
17 IDEA HERE IS THAT TRANSPLANTED CELLS ARE GOING TO
18 RESCUE PHOTORECEPTORS AND RESTORE VISION.

19 DR. KLASSEN HAS, LIKE I SAID, HE'S GOT FDA
20 APPROVAL AND MOVING FORWARD WITH ENROLLING PATIENTS
21 AT A GOOD RATE. HE'S FOLLOWING UP WITH THE
22 PATIENTS, AND HE WILL CONTINUE ENROLLING PATIENTS TO
23 AMOUNT TO 16 WITHIN THIS YEAR.

24 THE LAST GRANT THAT WE HAVE IS FOR DR.
25 WANG AT CEDARS-SINAI. AND DR. WANG IS A LITTLE BIT

BARRISTERS' REPORTING SERVICE

1 BEHIND THOSE TWO OTHER PROGRAMS. HER PROGRAM
2 STARTED NOT TOO LONG AGO. SHE'S IN THE PROCESS.
3 AGAIN, SHE'S WORKING ON INJECTING CELLS THIS TIME
4 SUBRETINALLY FOR, AGAIN, TO RESTORE VISION IN
5 RETINITIS PIGMENTOSA PATIENTS. HER CELL TYPE IS
6 MORE NEURONAL-LIKE, AND IT'S SUPPOSED TO BE MAYBE A
7 BETTER OPTION OR A DIFFERENT OPTION MAYBE IS THE
8 BETTER WORD. AND, AGAIN, THE HOPE IS THAT HER
9 PATIENT SELECTION WILL PROVIDE RESTORATION OF VISION
10 TO THESE PATIENTS.

11 SO SHE'S IN THE PROCESS WITH HER STAFF IN
12 MANUFACTURING CLINICAL GRADE CELLS, LEARNING MORE
13 ABOUT MECHANISM OF ACTION OF THE CELL TYPE THEY'VE
14 SELECTED, CONDUCTING PRECLINICAL STUDIES. AND THE
15 HOPE IS THAT THEY WILL FINALIZE THEIR APPLICATION SO
16 THEY CAN DO IND FILING AND GET FDA APPROVAL FOR
17 START OF CLINICAL TRIALS.

18 SO IN A NUTSHELL, WE HAVE THREE PROGRAMS,
19 AS THAT SHAMROCK DIAGRAM SHOWS, TWO IN RP, RETINITIS
20 PIGMENTOSA, ONE IN AMD, AND THEY'RE PROGRESSING
21 NICELY. AND WE ARE, WITH YOUR HELP, GOING TO
22 MONITOR THEIR PROGRESS TO LEAD TO OPTIMAL
23 RESTORATION OF VISION TO THESE PATIENTS. AND THANK
24 YOU. ANY QUESTIONS?

25 DR. DULIEGE: YOU MAY HAVE SAID IT, BUT I

BARRISTERS' REPORTING SERVICE

1 ONLY REALIZE ON YOUR SLIDES, CLEARLY THERE'S NO
2 TREATMENT FOR RP. SO IT'S REALLY AN ESSENTIAL
3 AVENUE HOPEFULLY. EVEN FOR AMD, WHAT THIS IS
4 TARGETING IS THE DRY AMD FOR WHICH, IF I'M CORRECT,
5 THERE'S ABSOLUTELY NO TREATMENT. AND IT'S EXTREMELY
6 PREVALENT, AS YOU SAID, AS OPPOSED WET AMD FOR WHICH
7 ADMITTEDLY THERE IS SOME REASONABLE TREATMENT. SO
8 THIS IS AN UNMET MEDICAL NEED, BUT OF MEGA
9 PROPORTION; IS THAT RIGHT?

10 DR. CREASEY: CORRECT. CORRECT. THANKS
11 FOR THAT NOTE. I THINK THAT'S IMPORTANT.

12 CHAIRMAN THOMAS: OTHER QUESTIONS AND
13 COMMENTS OF EITHER DOCTOR?

14 MR. JUELSGAARD: JUST TO BE CLEAR, YOU
15 SAID THAT TWO OF THESE PROJECTS INVOLVED RETINITIS
16 PIGMENTOSA AND ONE INVOLVED DRY AMD, AND YET THE
17 THREE SLIDES, THE KLASSEN SLIDE -- MAYBE I'M WRONG
18 HERE. OKAY. THE FIRST ONE DOESN'T. I DIDN'T GET
19 UP TO THAT SLIDE. IGNORE MY QUESTION.

20 DR. CREASEY: THANK YOU.

21 DR. FINI: THE TWO STUDIES THAT ARE
22 IMPLANTING RETINAL PROGENITOR CELLS, I WONDER IF YOU
23 CAN COMMENT ON THIS. I THINK THE EYE IN THIS CASE
24 MIGHT BE SORT OF LEADING THE WAY FOR OTHER STUDIES
25 LIKE THIS IN SPINAL CORD INJURIES OR OTHER TYPES OF

BARRISTERS' REPORTING SERVICE

1 NEURAL INJURIES. IN FACT, I THINK THIS MAY BE A
2 LEADING STUDY, ONE OF THE FIRST FORGING THE WAY
3 STUDIES, FOR IMPLANTATION OF NEURAL STEM CELLS,
4 ACTUAL NEURAL STEM CELLS.

5 DR. CREASEY: DR. WANG'S PROGRAM IS THE
6 ONE THAT'S DOING THAT, YES.

7 DR. FINI: AND WOULD YOU AGREE THAT THE
8 EYE IS IN THIS CASE LEADING THE WAY FOR OTHER NEURAL
9 STUDIES?

10 DR. CREASEY: ABSOLUTELY. YOU'RE
11 ABSOLUTELY CORRECT. IN FACT, I WAS GOING TO START
12 OUT BY SAYING THAT. I GUESS I'M LEARNING THAT OUR
13 MISSION IS NOT TO HYPE. AND SO THE KEY HERE IS TO
14 SAY THAT IT'S AN OPTIMAL PART OF THE BODY TO
15 INVESTIGATE THE TRUE POTENTIAL OF STEM CELLS, AND I
16 FEEL VERY LUCKY TO BE ABLE TO WORK ON THAT. THANK
17 YOU.

18 CHAIRMAN THOMAS: I HAVE A QUESTION,
19 DR. CREASEY. ONE OF THE QUESTIONS THAT ALL OF US
20 GET ASKED ALL THE TIME, ANYBODY CONNECTED TO CIRM,
21 IS SO WHAT DO YOU THINK HAS THE GREATEST CHANCE OF
22 WORKING FIRST, WHICH, OF COURSE, IS ALWAYS AN
23 IMPOSSIBLE QUESTION. BUT ONE OF THE ANSWERS THAT
24 ONE HEARS BANDIED ABOUT FOR A VARIETY OF REASONS IS
25 RESEARCH DONE ON THE EYE. I'M JUST CURIOUS WHAT

BARRISTERS' REPORTING SERVICE

1 YOUR TAKE IS ON THAT QUESTION. FEEL FREE TO SAY
2 THAT IT'S TOO SPECULATIVE AND CAN'T ANSWER.

3 DR. CREASEY: I'M GOING TO STATE A LITTLE
4 BIT OF MY OWN BIAS -- THIS IS NOT CIRM'S -- BECAUSE
5 OF I'VE HAD OVER 20 SOME YEARS OF EXPERIENCE IN
6 DEVELOPING DRUGS ALL THE WAY TO MARKET. AND THIS IS
7 MY -- I'VE HAD TWO OTHER PROGRAMS IN THE STEM CELL
8 AREA WORKING FOR A FOR-PROFIT ORGANIZATION. MY
9 SENSE IS THAT LOCALIZED ENVIRONMENTS WHERE YOU
10 IMPLANT CELLS THAT HAVE THE POTENTIAL OF NOT
11 PROLIFERATING, BUT ACTUALLY MAINTAINING A FUNCTION
12 IS AN IDEAL SITUATION TO TEST THE HYPOTHESIS.

13 SO WE LUCKED OUT THAT WE HAVE THREE
14 PROGRAMS HERE FOR OPHTHALMOLOGY. SO MY SENSE IS
15 THAT IF THE STEM CELLS THAT WERE SELECTED ARE GOING
16 TO PERFORM, THIS IS THE IDEAL ENVIRONMENT.

17 CHAIRMAN THOMAS: THAT'S A MUCH BETTER
18 ANSWER THAN I USUALLY GET. OKAY. THANK YOU. ANY
19 OTHER QUESTIONS FOR DR. CREASEY? OKAY. THANK YOU,
20 BOTH OF YOU, FOR THAT PRESENTATION.

21 OKAY. ONTO THE ITEM WHICH EVERYBODY HAS
22 BEEN WAITING FOR, MR. HARRISON, ON UPDATES TO THE
23 CIRM CONFLICT OF INTEREST LAWS.

24 MR. HARRISON: WHAT YOU'VE ALL BEEN
25 WAITING FOR. THIS ISN'T SO MUCH OF AN UPDATE AS IT

BARRISTERS' REPORTING SERVICE

1 IS A REMINDER OF THE VERY COMPLEX SET OF LAWS THAT
2 APPLY TO EACH OF YOU AS A PUBLIC OFFICIAL IN THE
3 STATE OF CALIFORNIA. MANY OF YOU PROBABLY WEREN'T
4 FAMILIAR WITH THESE RULES WHEN YOU AGREED TO TAKE ON
5 THIS ROLE. AND PERHAPS IF YOU HAD BEEN, YOU WOULD
6 HAVE SAID THANK YOU, BUT NO THANKS. SENATOR TORRES
7 KNOWS FROM A LONG LIFETIME IN THE PUBLIC WORLD SOME
8 OF THESE RULES ARE BOTH COMPLEX AND
9 COUNTERINTUITIVE, AND THERE ARE MANY TRAPS FOR BOTH
10 THE WARY AND THE UNWARY ALONG THE WAY.

11 SO MY GOAL HERE TODAY IS NOT TO DESCRIBE
12 TO YOU IN GREAT DETAIL THESE RULES OR CALL UPON YOU
13 TO STUDY THEM. IT'S REALLY TO KIND OF HIGHLIGHT
14 SOME OF THE TRAPS AND SOME OF THE ISSUES THAT HAVE
15 CAUSED PROBLEMS FOR OTHER PUBLIC OFFICIALS BECAUSE
16 ONE OF MY GOALS IS TO MAKE SURE THAT NONE OF YOU GET
17 INTO TROUBLE.

18 MY FIRM HAS A LONG HISTORY OF PRACTICING
19 IN THIS AREA. IN FACT, ONE NEWSPAPER REFERRED TO US
20 AS SPECIALIZING IN STUPID PUBLIC OFFICIAL TRICKS.
21 AND I WANT TO MAKE SURE THAT NONE OF YOU END UP IN
22 THAT PARTICULAR HEADLINE.

23 LET ME FIRST TALK ABOUT A TASK THAT IS
24 PROBABLY ON MANY OF YOUR PLATES RIGHT NOW, AND THAT
25 IS THE ANNUAL OBLIGATION TO FILE A FORM 700 IN WHICH

BARRISTERS' REPORTING SERVICE

1 YOU DISCLOSE YOUR VARIOUS ECONOMIC INTERESTS,
2 INCLUDING GIFTS, INVESTMENTS, SOURCES OF INCOME,
3 ETC. I KNOW THAT THIS IS A TEDIOUS TASK, THAT IT
4 CAN BE TIME-CONSUMING, AND THAT THERE IS A TENDENCY
5 TO JUST GET IT DONE QUICKLY AND GET IT FILED, BUT I
6 WANT TO MAKE ONE CAUTIONARY NOTE HERE.

7 FIRST OF ALL, THE FAIR POLITICAL PRACTICES
8 COMMISSION, WHICH IS THE STATE AGENCY CHARGED WITH
9 ENFORCING THE LAW, ACTUALLY MONITORS AND REVIEWS
10 STATEMENTS OF ECONOMIC INTEREST. AND THEY ROUTINELY
11 FINE OFFICIALS FOR FILING LATE, FAILING TO
12 ADEQUATELY DISCLOSE YOUR ECONOMIC INTERESTS, OR
13 FAILING TO FILE AT ALL. SO LET ME JUST GIVE TWO
14 QUICK ANECDOTES.

15 A FEW YEARS AGO CALPERS, THE STATE PENSION
16 SYSTEM, WAS UNDER SCRUTINY BECAUSE OF THE CONDUCT OF
17 ITS THEN CEO AND A MEMBER OF ITS BOARD. AS A RESULT
18 OF THAT, IT BECAME CLEAR THAT MANY INVESTMENT FIRMS
19 THAT DID BUSINESS WITH CALPERS WERE MAKING GIFTS TO
20 CALPERS EMPLOYEES AND BOARD MEMBERS. SO THE FAIR
21 POLITICAL PRACTICES COMMISSION CAME UP WITH A GREAT
22 IDEA. THEY DECIDED THAT THEY WOULD SUBPOENA EVERY
23 SINGLE INVESTMENT MANAGEMENT FIRM THAT WORKED WITH
24 CALPERS AND ASK THEM FOR A RECORD OF THE GIFTS THAT
25 THEY PROVIDED TO CALPERS OFFICIALS OVER A PERIOD OF

BARRISTERS' REPORTING SERVICE

1 FOUR YEARS.

2 CALPERS OFFICIALS KNEW THAT THEY WERE
3 GOING TO BE SUBJECT TO THIS, SO THEY WERE ENCOURAGED
4 TO VOLUNTARILY COMPLY. MANY OF THEM DID. AS A
5 RESULT OF THOSE SUBPOENAS, THE FPPC LEARNED THAT
6 MORE THAN TWO DOZEN CALPERS OFFICIALS HAD RECEIVED
7 GIFTS WHICH THEY FAILED TO REPORT. AND THE AGENCY
8 THEN IMPOSED FINES ON THOSE OFFICIALS, AND THERE
9 WERE MANY ARTICLES ABOUT IT IN THE *SACRAMENTO BEE*
10 AND OTHER PAPERS. SO IT WAS AN EMBARRASSMENT AS
11 WELL AS BEING A FINANCIAL COST FOR THESE
12 INDIVIDUALS.

13 THE FPPC, REALIZING IT HAD A GREAT THING
14 GOING, DECIDED THAT IT WOULD DO THIS AT THE LOCAL
15 LEVEL AS WELL. SO IN ONE CASE, ONE INVESTMENT FIRM
16 WHICH IT SUBPOENAED, THE INVESTMENT FIRM REPORTED
17 THAT IT HAD MADE GIFTS TO 312 OFFICIALS. OF THOSE
18 312, 282 OF THEM HAD NOT DISCLOSED THE GIFTS THEY
19 RECEIVED. GUESS WHAT. THEY ALL ENDED UP PAYING A
20 FINE OR RECEIVING A WARNING LETTER FROM THE FPPC.

21 SO THIS RESPONSIBILITY IS CHALLENGING AT
22 TIMES, BUT IT'S IMPORTANT THAT YOU TAKE THE TIME TO
23 DO IT RIGHT BECAUSE WE DON'T WANT YOU TO END UP IN A
24 POSITION WHERE THE FPPC IS BREATHING DOWN YOUR NECK.

25 THE NEXT THING I WANTED TO TOUCH ON

BARRISTERS' REPORTING SERVICE

1 BRIEFLY IS THE STATE CONFLICT OF INTEREST LAW. AND
2 THERE ARE TWO PRIMARY LAWS THAT APPLY HERE. ONE IS
3 THE POLITICAL REFORM ACT WHICH GOVERNS CONFLICTS OF
4 INTEREST GENERALLY. THE OTHER IS GOVERNMENT CODE
5 SECTION 1090 WHICH APPLIES SPECIFICALLY IN THE
6 CONTEXT OF CONTRACTS.

7 THE RULE ITSELF IS ACTUALLY PRETTY
8 STRAIGHTFORWARD. YOU'RE NOT PERMITTED TO
9 PARTICIPATE IN A DECISION IF IT'S REASONABLY
10 FORESEEABLE THAT THAT DECISION IS GOING TO HAVE A
11 MATERIAL FINANCIAL EFFECT ON ONE OF YOUR ECONOMIC
12 INTERESTS. THE CHALLENGE IS THAT EACH OF THOSE
13 RULES IS A DEFINED TERM. AND, AGAIN, SOME OF THESE
14 DEFINITIONS ARE NOT INTUITIVE. SO, FOR EXAMPLE, IF
15 YOU EARN INCOME FROM A GOVERNMENT AGENCY, IT'S NOT
16 CONSIDERED TO BE INCOME UNDER THE LAW. IT DOESN'T
17 CONSTITUTE A FINANCIAL INTEREST.

18 LIKewise, UNDER FORM 700, YOU'RE REQUIRED
19 TO DISCLOSE INVESTMENTS IN COMPANIES IN WHICH YOU
20 OWN A 10-PERCENT INTEREST OR GREATER. AND AS PART
21 OF THAT, YOU'RE REQUIRED TO DISCLOSE YOUR PRO RATA
22 SHARE OF INCOME FROM ANY BUSINESSES OF THAT BUSINESS
23 TO THE EXTENT THEY'RE \$10,000 OR MORE.
24 UNFORTUNATELY, THE THRESHOLD FOR CONFLICTS OF
25 INTEREST IS ONLY \$500. SO IT'S A LITTLE BIT

BARRISTERS' REPORTING SERVICE

1 MISLEADING AND, AS I SAID, CAN CREATE TRAPS.

2 ONE OF THE IMPORTANT THINGS TO REMEMBER
3 HERE IS THAT THIS APPLIES NOT ONLY TO DECISIONS IN
4 WHICH YOU DIRECTLY PARTICIPATE, BUT EVEN DECISIONS
5 IN WHICH YOU ARE SOMEHOW INVOLVED OR ATTEMPT TO
6 INFLUENCE. LET ME GIVE YOU ONE EXAMPLE OF THAT.

7 LAST YEAR THE FPPC FINED A MEMBER OF A
8 PLANNING COMMISSION, A LOCAL PLANNING COMMISSION.
9 HE WAS AN EMPLOYEE OF A DEVELOPER, AND A PLANNING
10 COMMISSION EMPLOYEE CALLED HIM IN HIS CAPACITY AS
11 VICE PRESIDENT OF THIS DEVELOPMENT COMPANY TO ASK
12 HIM A QUESTION ABOUT A PENDING PROJECT THAT THE
13 DEVELOPMENT COMPANY HAD. AND IT RELATED TO THE
14 REMOVAL OF TREES ON THE PROJECT. SHE PROVIDED HIM
15 WITH AN ESTIMATE OF THE COST. HE SAID THAT SEEMS
16 KIND OF HIGH. SHE AGREED TO REDUCE THE ESTIMATE AS
17 LONG AS THE DEVELOPMENT COMPANY AGREED TO PAY ANY
18 OVERAGE. SO THEY AGREED AND WENT OFF ON THEIR MERRY
19 WAYS.

20 WELL, WHEN THE FPPC LEARNED OF THIS, THEY
21 COMMENCED AN ENFORCEMENT ACTION AGAINST HIM AND
22 FINED HIM \$6,000 BECAUSE HE HAD, AGAIN, WEARING HIS
23 DEVELOPMENT COMPANY HAT, ATTEMPTED TO INFLUENCE THE
24 PLANNING DEPARTMENT EMPLOYEE, EVEN THOUGH SHE
25 INITIATED THE CONTACT AND HE WAS CLEARLY ACTING

BARRISTERS' REPORTING SERVICE

1 WEARING HIS DEVELOPMENT COMPANY HAT. SO THIS IS AN
2 EXAMPLE OF HOW AGGRESSIVELY THE FPPC ENFORCES THESE
3 RULES. BY THE WAY, THIS DECISION, THE REMOVAL OF
4 THE TREES, WASN'T EVEN SOMETHING THAT WOULD HAVE
5 EVER COME BEFORE THE PLANNING COMMISSION. IT WASN'T
6 SOMETHING THAT WAS WITHIN THEIR SCOPE OF AUTHORITY,
7 AND NONETHELESS THE FPPC SOUGHT HIM OUT AND FINED
8 HIM FOR IT.

9 THERE ARE ALSO REALLY COMPLEX RULES
10 RELATING TO GIFTS, AND THE FPPC TAKES THESE VERY
11 SERIOUSLY AS WELL. TWO YEARS AGO IT FINED A MEMBER
12 OF THE STATE ASSEMBLY WHO HAD RECEIVED TWO TICKETS
13 TO THE 49ERS. THEY FINED HIM \$1,000 BECAUSE THE
14 TICKETS CAME FROM A LOBBYIST AND OFFICIALS ARE
15 PROHIBITED FROM ACCEPTING GIFTS WITH A VALUE OF MORE
16 THAN \$10 PER MONTH FROM A LOBBYIST. THE 49ERS
17 WEREN'T EVEN THAT GOOD, AND THEY LOST THAT GAME, AND
18 HE ENDED UP PAYING A THOUSAND BUCKS. SO THINK
19 CAREFULLY ABOUT THAT.

20 LET ME TALK BRIEFLY ABOUT THE OTHER
21 CONFLICT OF INTEREST LAW THAT APPLIES. THIS ONE IS
22 PARTICULARLY HARSH. THIS IS GOVERNMENT CODE SECTION
23 1090. IT PROHIBITS A PUBLIC OFFICIAL FROM BEING
24 FINANCIALLY INTERESTED IN A CONTRACT IN BOTH HIS
25 PRIVATE CAPACITY AND HIS OR HER PERSONAL CAPACITY.

BARRISTERS' REPORTING SERVICE

1 AND THERE ARE REALLY TRULY SOME HORROR STORIES
2 INVOLVING GOVERNMENT CODE SECTION 1090.

3 SOME OF YOU MAY REMEMBER A FORMER
4 SUPERINTENDENT OF PUBLIC INSTRUCTION, BILL HOENIG,
5 WHO WAS ACTUALLY CONVICTED OF A FELONY BECAUSE HE
6 HAD BEEN INVOLVED IN A DECISION BY THE STATE
7 DEPARTMENT OF EDUCATION TO DIRECT GRANT FUNDS TO AN
8 AGENCY, A NONPROFIT AGENCY, THAT EMPLOYED HIS WIFE.
9 AND THE NONPROFIT AGENCY WAS NOT INTENDING TO USE
10 THE FUNDS FOR HER SALARY, BUT NONETHELESS, THE COURT
11 CONCLUDED HE HAD VIOLATED THIS RULE BECAUSE, BY
12 HAVING THESE FUNDS FROM THE STATE, IT FREED UP OTHER
13 FUNDS THAT COULD THEN BE USED TO PAY HER SALARY.

14 PERHAPS THE ONE CASE THAT STICKS OUT MOST
15 IN MY MIND UNDER THIS LAW IS A CASE THAT INVOLVED A
16 CITY COUNCIL MEMBER IN ALBANY WHO SOUGHT ADVICE FROM
17 A CITY ATTORNEY BEFORE DOING ANYTHING. THIS
18 INVOLVED, AGAIN, A DEVELOPMENT, AND THE CITY, AS
19 PART OF ITS PROPOSAL TO APPROVE THE DEVELOPMENT
20 AGREEMENT, ASKED THE DEVELOPER TO CREATE A NEW CITY
21 PARK. THE DEVELOPER ACQUIRED THE LAND FROM THIS
22 COUNCILMEMBER FOR PURPOSES OF CREATING THIS PUBLIC
23 PARK. CITY COUNCIL MEMBER SOUGHT ADVICE FROM THE
24 CITY ATTORNEY. IS THIS OKAY? CITY ATTORNEY SAID
25 IT'S OKAY AS LONG AS YOU RECUSE YOURSELF. SO WHEN

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1 THE DEVELOPMENT AGREEMENT CAME BEFORE THE CITY
2 COUNCIL FOR A VOTE, HE RECUSED HIMSELF AND THE REST
3 OF THE COUNCIL WENT AHEAD AND APPROVED IT.

4 SO THE END RESULT WAS THAT THE \$260,000
5 THAT HE RECEIVED IN PAYMENT FOR THIS PROPERTY HAD TO
6 BE DISGORGED TO THE CITY, WHICH WAS THEN ALSO
7 ALLOWED TO KEEP THE LAND FOR USE AS A PARK. SO HE
8 HAD ACTUALLY RELIED ON THE ADVICE OF THE CITY
9 ATTORNEY AND, NONETHELESS, SUFFERED THESE KINDS OF
10 CONSEQUENCES. SO IT IS A LAW THAT IS VERY
11 AGGRESSIVELY AND STRICTLY ENFORCED. SO IT'S
12 SOMETHING TO BE VERY WARY OF. IT ALSO APPLIES NOT
13 JUST TO THE CONTRACT DECISION ITSELF, BUT THINGS
14 THAT LEAD UP TO THE CONTRACT DECISION.

15 SO IN ONE CASE ANOTHER COUNCILMEMBER
16 PARTICIPATED IN THE DEVELOPMENT OF AN RFP FOR A
17 PLUMBING CONTRACT, SUBSEQUENTLY RESIGNED HIS
18 PLUMBING COMPANY, AND THEN SUBMITTED A BID AND WON.
19 AND THE COURT FOUND THAT THE CONTRACT WAS VOID AND
20 THAT THE COMPANY HAD TO DISGORGE THE MONEY IT HAD
21 RECEIVED PURSUANT TO IT BECAUSE HE HAD PARTICIPATED
22 IN THOSE EARLY DISCUSSIONS ABOUT DEVELOPING THE
23 REQUEST FOR PROPOSALS.

24 WE HAVE SPECIAL RULES FOR CIRM. UNDER
25 ORDINARY CIRCUMSTANCES, IF A SINGLE MEMBER OF A

BARRISTERS' REPORTING SERVICE

1 BOARD HAS AN INTEREST IN A CONTRACT UNDER GOVERNMENT
2 CODE SECTION 1090, THEN THE ENTIRE BOARD IS PRESUMED
3 TO BE TAINTED AND CANNOT APPROVE THE CONTRACT. THEY
4 CAN'T EVEN CONSIDER IT. SO PROPOSITION 71 MODIFIED
5 THE APPLICATION OF THIS LAW TO THIS BOARD SO THAT IN
6 AN INSTANCE WHERE ONE OF YOU HAS AN INTEREST IN A
7 CONTRACT, SAY BECAUSE YOU'RE AN EMPLOYEE OF THAT
8 INSTITUTION, AS LONG AS YOU RECUSE YOURSELF, THE
9 REMAINDER OF THE BOARD CAN GO AHEAD AND APPROVE THE
10 CONTRACT WITHOUT VIOLATING THE LAW.

11 LAST THING I'D LIKE TO TOUCH ON BRIEFLY,
12 THIS MAY BE MORE IMPORTANT DOWN THE ROAD IF THERE IS
13 ANOTHER BALLOT MEASURE, BUT THERE IS A PRETTY STRICT
14 PROHIBITION ON THE USE OF PUBLIC RESOURCES FOR
15 POLITICAL PURPOSES. AND POLITICAL PURPOSES ARE
16 DEFINED TO INCLUDE ADVOCACY FOR A BALLOT MEASURE.
17 AND ALTHOUGH THERE IS AN EXCEPTION FOR THE DE
18 MINIMIS USE OF PUBLIC RESOURCES FOR ADVOCACY, THE
19 COUNTY OF SANTA CLARA WAS SUBJECT BOTH TO AN
20 INVESTIGATION BY THE ATTORNEY GENERAL AS WELL AS A
21 CIVIL LAWSUIT BECAUSE A MEMBER OF THE BOARD OF
22 SUPERVISORS ASKED A MEMBER OF HER STAFF ON HER LUNCH
23 HOUR TO SEND AN E-MAIL TO HER E-MAIL LIST, WHICH
24 INCLUDED ABOUT 5,000 PEOPLE, ATTACHING AN EDITORIAL
25 IN THE *SAN JOSE MERCURY NEWS* OPPOSING A BALLOT

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1 MEASURE THAT WAS SCHEDULED TO BE ON THE BALLOT IN
2 NOVEMBER.

3 SO THE TEN MINUTES THAT STAFF MEMBER SPENT
4 DRAFTING THE E-MAIL, BECAUSE IT INCLUDED A LINK
5 WHICH INCLUDED ADVOCACY AGAINST THE BALLOT MEASURE,
6 RESULTED IN A LENGTHY INVESTIGATION BY THE ATTORNEY
7 GENERAL TO DETERMINE WHETHER OR NOT THE STAFF MEMBER
8 AND THE SUPERVISOR HAD VIOLATED THE PROHIBITION
9 AGAINST THE USE OF PUBLIC RESOURCES, AND THEN A YEAR
10 AND A HALF LONG LAWSUIT OVER THAT USE. SO, AGAIN,
11 THIS IS AN EXAMPLE WHERE EVEN IF IT'S JUST A REALLY
12 SMALL THING, THE COST AND CONSEQUENCES CAN FAR
13 EXCEED ANY VALUE YOU GET BY EVEN A SMALL USE LIKE
14 THAT.

15 SO THIS IS ALL JUST A VERY BRIEF WAY OF
16 REMINDING YOU THAT THESE LAWS ARE IMPORTANT AND THAT
17 THEY CAN HAVE FAR-REACHING CONSEQUENCES.

18 AND THE LAST THOUGHT I WILL LEAVE YOU
19 WITH, PEOPLE OFTEN ASK ME ABOUT THESE RULES AND WHY
20 IT TAKES A LAWYER TO UNDERSTAND AND EXPLAIN THEM TO
21 THEM. MY GENERAL RESPONSE IS YOU DON'T REALLY NEED
22 A LAWYER MOST OF THE TIME BECAUSE IF IN YOUR GUT,
23 WHEN YOU'RE ASKED TO DO SOMETHING AND IT DOESN'T
24 QUITE FEEL RIGHT, THEN IT PROBABLY ISN'T. AND BY
25 ALL MEANS, IF YOU ARE EVER IN THAT KIND OF

BARRISTERS' REPORTING SERVICE

1 SITUATION, PLEASE PAUSE AND ASK US ON THE CIRM TEAM
2 FIRST SO THAT WE CAN GIVE YOU ADVICE. AND IF WE'RE
3 WRONG, SORRY ABOUT THAT; BUT AS THE COURTS HAVE
4 CONCLUDED, ADVICE OF COUNSEL IS NOT A DEFENSE. SO
5 APPRECIATE YOUR TIME.

6 CHAIRMAN THOMAS: WHO KNEW THAT MR.
7 HARRISON HAD A SENSE OF HUMOR.

8 MR. JUELSGAARD: JAMES, SO ADVICE OF
9 COUNSEL IS NOT A DEFENSE FOR THESE KINDS OF ACTIONS?

10 MR. HARRISON: FOR PURPOSES OF GOVERNMENT
11 CODE SECTION 1090, THAT'S CORRECT. WE'LL RETURN THE
12 FEES TO CIRM.

13 CHAIRMAN THOMAS: ANY OTHER QUESTIONS FOR
14 MR. HARRISON ON THAT UPLIFTING PRESENTATION?
15 HEARING NONE, I BELIEVE THAT CONCLUDES TODAY'S
16 AGENDA UNLESS WE HAVE ANY PUBLIC COMMENT OF A
17 GENERAL NATURE. WE DO. HOW ARE YOU, JUDY?

18 MS. ROBERSON: GOOD. I'M JUDY ROBERSON
19 FROM SACRAMENTO. I'M A VOLUNTEER PATIENT ADVOCATE
20 FOR HUNTINGTON'S DISEASE. I JUST HAVE A SHORT THANK
21 YOU TO THE BOARD.

22 I'LL SHOW YOU THIS PRESS RELEASE FROM
23 YESTERDAY. THANKS TO DON GIBBONS, EVERYBODY GOT
24 THAT IN THEIR E-MAIL BOX THIS MORNING.

25 SO YESTERDAY THE UC DAVIS HUNTINGTON'S

BARRISTERS' REPORTING SERVICE

1 DISEASE TEAM, THEIR PAPER GOT PUBLISHED IN THE
2 *JOURNAL OF MOLECULAR THERAPY*, "HUMAN STEM CELLS
3 TARGET HUNTINGTON'S DISEASE." "SUCCESSFUL APPROACH
4 BY UC DAVIS TEAM SHOWS DIMINISHED NEURON LOSS,
5 REDUCED SYMPTOMS, AND EXTENDED LIFE IN ANIMAL MODELS
6 OF HUNTINGTON'S DISEASE."

7 SO IT'S A BIG DEAL. IT WAS FUNDED BY
8 CIRM. SO THANK YOU. THANK YOU SO MUCH.

9 AND FROM THE THOUSANDS OF PEOPLE LIKE
10 FAMILIES LIKE MINE IN THE HD COMMUNITY, WE WANT TO
11 THANK DRS. VICKIE WHEELLOCK AND JAN NOLTA AT UC DAVIS
12 AND THEIR TEAMS FOR WORKING SO HARD FOR YEARS TO TRY
13 AND FIND A THERAPY FOR PEOPLE SUFFERING WITH
14 HUNTINGTON'S DISEASE.

15 FOR MY FAMILY, WE'VE LOST FOUR MEMBERS
16 INCLUDING MY HUSBAND, AND MY SISTER-IN-LAW IS SICK,
17 AND THERE'S 17 LOVED ONES IN MY FAMILY AT RISK FOR
18 HUNTINGTON'S. AS OF TODAY, THERE'S STILL NOT ONE
19 TREATMENT FOR HUNTINGTON'S. AND THIS IS A
20 HEREDITARY DEGENERATIVE, PROGRESSIVE BRAIN DISEASE
21 WITH NO THERAPIES. THEY SAID MAYBE BLUEBERRIES
22 WOULD HELP, BUT THAT'S IT.

23 SO I WANT TO THANK CIRM AGAIN FOR FUNDING
24 THIS IMPORTANT RESEARCH AT UC DAVIS. THANK YOU.

25 CHAIRMAN THOMAS: THANK YOU, JUDY. ANY

BARRISTERS' REPORTING SERVICE

1 OTHER GENERAL PUBLIC COMMENTS? HEARING NONE, WE
2 STAND ADJOURNED. OUR NEXT IN-PERSON MEETING IS IN
3 JUNE, AND OUR NEXT MEETING IS NEXT MONTH. SO WE
4 WILL SEE EVERYBODY DOWN THE ROAD. THANK YOU VERY
5 MUCH.

6 (THE MEETING WAS THEN CONCLUDED AT
7 02:39 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 PROCEEDINGS BEFORE THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD AT THE LOCATION INDICATED BELOW

THE WESTIN SAN FRANCISCO AIRPORT
1 OLD BAYSHORE HIGHWAY
MILLBRAE, CALIFORNIA
ON
MARCH 16, 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.

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