

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

LOCATION: AS INDICATED ON THE AGENDA

DATE: TUESDAY, JANUARY 20, 2015
4 P.M.

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

BRS FILE NO.: 97124

BARRISTERS' REPORTING SERVICE

I N D E X

ITEM DESCRIPTION	PAGE NO.
CALL TO ORDER	3
ROLL CALL	3
CONSIDERATION OF ADOPTION OF THE INTERIM GRANTS ADMINISTRATION POLICY FOR CLINICAL STAGE PROGRAMS	4
PUBLIC COMMENT	NONE

BARRISTERS' REPORTING SERVICE

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

TUESDAY, JANUARY 20, 2015; 4:00 P.M.

CHAIRMAN SHEEHY: SO I THINK WE'RE READY
TO CALL TODAY'S MEETING OF THE SCIENTIFIC
SUBCOMMITTEE TO ORDER. MARIA, WOULD YOU LIKE TO
CALL THE ROLL?

MS. BONNEVILLE: SURE.

CHAIRMAN SHEEHY: PLEASE.

MS. BONNEVILLE: MICHAEL FRIEDMAN.

DR. FRIEDMAN: HERE.

MS. BONNEVILLE: DAVID HIGGINS.

MR. HIGGINS: HERE.

MS. BONNEVILLE: BURT LUBIN.

DR. LUBIN: HERE.

MS. BONNEVILLE: SHLOMO MELMED.

DR. MELMED: HERE.

MS. BONNEVILLE: JEFF SHEEHY.

CHAIRMAN SHEEHY: HERE.

MS. BONNEVILLE: OS STEWARD.

DR. STEWARD: HERE.

MS. BONNEVILLE: ART TORRES. JONATHAN
THOMAS.

CHAIRMAN THOMAS: HERE.

MS. BONNEVILLE: KRISTINA VUORI.

DR. VUORI: HERE.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN SHEEHY: SO BEFORE WE BEGIN, ARE
2 THERE ANY MEMBERS OF THE PUBLIC AT ANY OF THE SITES?

3 (NO RESPONSE.)

4 SO THE ITEM WE HAVE ON OUR AGENDA TODAY IS
5 CONSIDERATION OF ADOPTION OF THE INTERIM GRANTS
6 ADMINISTRATION POLICY FOR CLINICAL STAGE PROGRAMS.
7 DO WE HAVE A PRESENTATION ON THAT, TEAM MEMBERS?

8 MR. THOMPSON: HI. I'M GABRIEL THOMPSON.
9 I'M THE DIRECTOR OF THE GRANTS MANAGEMENT AT CIRM.
10 SO I'M GOING TO BE DOING THE INTERIM REGULATIONS.
11 SO JUST KIND OF AS AN OVERVIEW, THESE WILL BE
12 INTERIM REGULATIONS THAT WILL GOVERN THE NEW AWARDS
13 THAT COME THROUGH OUR NEW THREE PROGRAMS. SO THESE
14 WOULD BE -- BECAUSE WE NEED REGULATIONS IN PLACE
15 BEFORE THOSE AWARDS ARE LAUNCHED AND BECAUSE WE HAVE
16 TIME CONSTRAINTS, WE ARE USING OUR AUTHORITY TO POST
17 INTERIM REGULATIONS FOR THESE NEW PROJECTS. THESE
18 INTERIM REGULATIONS WILL NOT APPLY TO ANY NEW CIRM
19 AWARDS, NOR WILL THEY APPLY TO ANY NEW BASIC OR
20 TRANSLATIONAL AWARDS. THEY WILL ONLY APPLY TO
21 BRAND-NEW CLINICAL STAGE AWARDS.

22 SO THESE INTERIM REGULATIONS WILL START
23 THE RULEMAKING PROCESS WITH THE OFFICE OF
24 ADMINISTRATIVE LAW. WE'LL HAVE 270 DAYS FOR THESE
25 INTERIM REGULATIONS TO BE IN PLACE BEFORE WE HAVE TO

BARRISTERS' REPORTING SERVICE

1 THEN GO GET FORMAL APPROVAL THROUGH OAL.

2 SO JUST BRIEFLY, OUR APPROACH ON PUTTING
3 THESE INTERIM REGULATIONS TOGETHER WERE TO TAKE
4 THINGS FROM THE CURRENT GRANTS ADMINISTRATION POLICY
5 THAT WE BELIEVE ARE ALIGNED WITH OUR NEW PROCESS AND
6 ONLY THOSE POLICIES, SO LOOKING AT POLICIES THAT
7 WEREN'T REALLY WORKING FOR US AND LEAVING THAT OUT
8 OF THE NEW INTERIM REGULATIONS, AND THEN ADDING ON
9 TOP OF THAT A LOT OF THE NEW CONCEPTS THAT OUR
10 PRESIDENT HAS PRESENTED ABOUT CIRM 2.0 AND THE
11 EFFICIENT APPLYING FOR AWARDS, ADMINISTERING OUR
12 AWARDS, REVIEWING OUR AWARDS, ETC. AND WE'LL GO
13 INTO SOME OF WHAT THOSE ARE ON THE NEXT SLIDE.

14 THEN WE ADDED A BUNCH OF LANGUAGE THAT HAD
15 OVER TIME BEEN PUT INTO OUR NOTICE OF GRANT AWARDS
16 THAT WERE NOT PROJECT SPECIFIC, THAT WE WERE JUST
17 ADDING TO ALL OF OUR AWARDS, BUT THAT WE THINK NEED
18 TO GO INTO OUR GRANTS ADMINISTRATION POLICY SO THAT
19 WHEN PEOPLE ARE APPLYING FOR CIRM FUNDING, THEY KNOW
20 WHAT THE REGULATIONS ARE, THAT THEY'RE NOT TERMS AND
21 CONDITIONS THAT ARE ADDED AT THE CONTRACTING STAGE
22 THAT THEY WOULDN'T HAVE KNOWN ABOUT. SO WE'RE
23 TRYING TO PUT MORE OF THAT INTO -- UP FRONT IN OUR
24 GRANTS ADMINISTRATION POLICY.

25 AND THEN FINALLY, JUST TRYING TO CLARIFY

BARRISTERS' REPORTING SERVICE

1 AND SIMPLIFY THE REGULATIONS WHERE WE CAN.
2 SO TO GO THROUGH SOME OF THE MAJOR
3 FEATURES OF THE INTERIM REGULATIONS, COUPLE THINGS
4 TO GO THROUGH. WE'RE NOW ESTABLISHING -- DEFINING
5 WHAT AN OPERATIONAL MILESTONE IS, AND WE'VE DEFINED
6 IT AS AN OBJECTIVE EVENT INDICATIVE OF PROJECT
7 PROGRESS THAT WILL HELP US DETERMINE HOW WE
8 STRUCTURE THE DISBURSEMENTS FOR THE AWARD AND TELLS
9 THE GRANTEE WHAT THE CONSEQUENCES FOR DELAYS IN NOT
10 ACHIEVING AN OPERATIONAL MILESTONE ARE.

11 WE NOW DEFINE SUSPENSION EVENTS AND THE
12 CONSEQUENCES FOR WHEN THESE EVENTS OCCUR. SO
13 SUSPENSION EVENTS WOULD BE PREDEFINED CONDITIONS
14 THAT WOULD TRIGGER A HOLD OF CIRM FUNDING UNTIL THE
15 SUSPENSION EVENT IS RESOLVED. SO WE'VE DEFINED THE
16 TERM "SUSPENSION EVENT." DEPENDING ON THE TYPE OF
17 PROJECT WE'RE FUNDING, WE WOULD COME UP WITH WHAT WE
18 THINK WOULD BE THE APPROPRIATE SUSPENSION EVENT.
19 THESE COULD BE THINGS SUCH AS A SERIOUS ADVERSE
20 EVENT THAT WAS DIRECTLY RELATED TO THE THERAPY THAT
21 WE WERE FUNDING. SO THINGS LIKE THAT. IF
22 CO-FUNDING THAT THEY COMMITTED TO IN THE APPLICATION
23 DIDN'T ACTUALLY MATERIALIZE AT SOME PART DURING THE
24 AWARD, THAT WOULD BE A CONDITION -- A SUSPENSION
25 EVENT WHICH WE WOULD THEN REVIEW AND DETERMINE

BARRISTERS' REPORTING SERVICE

1 WHETHER WE WOULD PROCEED WITH OUR FUNDING.

2 THE INTERIM REGS DESCRIBE THE BUDGET
3 REVIEW PROCESS. THIS IS WE WILL HAVE A TEAM OF
4 BUDGET PROFESSIONALS THAT WILL REVIEW THE BUDGETS ON
5 APPLICATIONS AS THEY COME IN. AND WE WILL DETERMINE
6 WHETHER -- THERE WILL BE A HIGH LEVEL BUDGET REVIEW,
7 AND THAT WILL DETERMINE WHETHER THEY CAN PROCEED TO
8 GWG OR SHOULD REAPPLY. AND THE CIRM PRESIDENT HAS
9 THE FINAL APPROVAL OVER THAT BUDGET REVIEW PROCESS.

10 CHAIRMAN THOMAS: MAYBE THIS IS FOR JEFF
11 AND OTHER BOARD MEMBERS. SO WHAT WILL BE THE GOAL
12 OF BUDGET REVIEW BY GWG MEMBERS GOING FORWARD?

13 MR. THOMPSON: RIGHT. SO THE GWG WILL
14 STILL HAVE BUDGET INPUT. SO THEY SHOULD STILL
15 REVIEW THE BUDGET AND PROVIDE COMMENTS WHEN THEY
16 THINK THERE'S PROBLEMS WITH THE BUDGET AS WELL AS
17 THE ICOC CAN CONTINUE TO MAKE BUDGET COMMENTS, AND
18 WE WILL STILL USE THOSE COMMENTS TO THEN NEGOTIATE
19 AWARDS DURING THE JUST-IN-TIME PHASE WERE THEY TO
20 REACH THAT POINT. SO WE WILL STILL ASK FOR BUDGET
21 COMMENTS DURING THE GWG.

22 DR. SAMBRANO: THIS IS GIL SAMBRANO. I
23 JUST WANT TO ADD A LITTLE BIT TO THAT. SO WE WILL
24 HAVE A PROCESS BY WHICH APPLICATIONS UNDERGO
25 SPECIFICALLY A BUDGET REVIEW, NOT BY THE GRANTS

BARRISTERS' REPORTING SERVICE

1 WORKING GROUP, BUT SEPARATELY. SO THAT WILL GIVE US
2 JUST A GENERAL SENSE. IF THE APPLICATION IS OFF BY,
3 SAY, 10 PERCENT OR MORE, WE HAVEN'T DEFINED EXACTLY
4 THE PERCENT THAT IT NEEDS TO BE WITHIN, BUT IF IT
5 FAILS THAT BUDGET REVIEW, IT DOES NOT GO TO
6 SCIENTIFIC REVIEW.

7 SO THE IDEA IS THAT THE GRANTS WORKING
8 GROUP WILL FOCUS ITS REVIEW ON THE OVERALL
9 SCIENTIFIC MERIT AND ON THOSE CRITERIA. AND SO OUR
10 INSTRUCTION TO REVIEWERS AT THAT POINT WILL BE THEY
11 WILL HAVE ACCESS TO THE BUDGET IF THEY IDENTIFY
12 SOMETHING THAT THEY WANT TO FLAG OR LET US KNOW
13 ABOUT, IT'S FINE. THE BUDGET THEY SHOULD BE LOOKING
14 AT AT THAT POINT IS ONE THAT HAS ALREADY BEEN
15 LARGELY REVIEWED AND WOULD BE REALLY MINOR ISSUES,
16 UNLESS IT HAPPENS TO BE SOMETHING THAT WAS CAUGHT
17 EARLIER, BUT ESSENTIALLY IT'S ALREADY DEALT WITH
18 BEFOREHAND. SO THE GRANTS WORKING GROUP WILL NOT
19 FOCUS ON THAT, AND IT WILL NOT IMPACT THEIR SCORING.
20 SO THE SCORE WILL NOT BE BASED ON BUDGET.

21 MR. THOMPSON: ANY QUESTIONS ABOUT THE
22 BUDGET REVIEW?

23 SO WE ALSO DESCRIBE IN THE REGULATIONS
24 THAT THE APPLICANT MUST COMMIT TO INITIATING WORK ON
25 THE AWARD WITHIN 45 DAYS OF ICOC APPROVAL. SO THAT

BARRISTERS' REPORTING SERVICE

1 WAS DIFFERENT IN THE GAP, SO WE HAD TO REVISE THAT
2 LANGUAGE. SO THAT'S NOW A REQUIREMENT.

3 WE ACTUALLY ARE ALSO DESCRIBING THE
4 CLINICAL ADVISORY PANELS. SO WE ARE DESCRIBING HERE
5 THE ROLE OF THE CLINICAL ADVISORY PANEL, BORROWING
6 SOME LANGUAGE FROM THE BYLAWS FOR THESE CLINICAL
7 ADVISORY PANELS, AND THOSE CLINICAL ADVISORY PANELS
8 ARE FORMED SUBJECT TO THE PRESIDENT'S APPROVAL.

9 WE HAVE REMOVED THE PRIOR APPROVAL
10 REQUIREMENTS FOR CARRY-FORWARD REBUDGETING AND
11 NO-COST EXTENSIONS. SO THIS IS SOMETHING OUR
12 CURRENT GAP REQUIRES FOR CURRENT ACTIVE AWARDS; BUT
13 BECAUSE WE'RE ACTUALLY PAYING ON THE OPERATIONAL
14 MILESTONE BASIS, IT ACTUALLY WON'T NEED
15 CARRY-FORWARD OR REBUDGETING OR NO-COST EXTENSION
16 REQUESTS ANYMORE. THIS IS KIND OF ADMINISTRATIVE
17 WORK THAT'S REQUIRED BASED ON BUDGET PERIODS.

18 FOR OUR NEW AWARDS WE NO LONGER HAVE
19 BUDGET PERIODS. WE WILL HAVE PERIODS TO GET TO AN
20 OPERATIONAL MILESTONE. SO AS LONG AS THEY'RE
21 GETTING TO THOSE OPERATIONAL MILESTONES, WE WILL
22 CONTINUE TO MAKE DISBURSEMENTS TO GET TO THE NEXT
23 OPERATIONAL MILESTONE. SO THIS REMOVES THE NEED FOR
24 PRIOR APPROVAL REQUESTS FOR THESE SPECIFIC
25 REQUIREMENTS.

BARRISTERS' REPORTING SERVICE

1 WE WILL STILL HAVE PRIOR APPROVAL REQUESTS
2 FOR A CHANGE OF SCOPE, CHANGE OF RESEARCH
3 ACTIVITIES, CHANGE OF PI, CHANGE OF INSTITUTION.
4 ALL THOSE THINGS REMAIN IN THERE. WE'RE JUST
5 REMOVING THESE THREE PARTS.

6 AND THEN FINALLY, WE DESCRIBE HOW AN
7 AWARDEE CAN USE POSTPROJECT SAVINGS. AT THE END OF
8 A PROJECT, AT THE END OF OUR AWARD, IF THE AWARDEE
9 HAS ACTUAL SAVINGS, AND WE DON'T EXPECT THIS TO
10 HAPPEN VERY OFTEN, IF AT ALL, BUT IF IT DOES, WE
11 WANTED TO PROVIDE AN INCENTIVE TO HAVE SAVINGS. AND
12 SO WE DESCRIBED THAT, SUBJECT TO CIRM'S PRIOR
13 APPROVAL, WE WOULD ALLOW THE AWARDEE TO USE ANY
14 POSTPROJECT SAVINGS TO PAY BACK ANY CO-FUNDING OVER
15 THE REQUIRED MINIMUM. SO IF THEY PUT IN MORE MONEY
16 DURING THE PROJECT PERIOD THAN WAS REQUIRED OF CIRM,
17 THEY CAN USE THE SAVINGS TO GO BACK TO THE MINIMUM
18 REQUIREMENT, OR THEY COULD USE THE FUNDING FOR ANY
19 OTHER PROJECT THAT IS ALIGNED WITH CIRM'S MISSION.

20 SO WE'VE DESCRIBED THAT USE IN THE GAP AS
21 WELL, OF COURSE, AGAIN, SUBJECT TO CIRM'S PRIOR
22 APPROVAL. SO WE WOULD HAVE A QUICK CHECK TO MAKE
23 SURE, ONE, THAT IT IS ALIGNED WITH CIRM'S MISSION,
24 AND, TWO, THAT THE USE OF THE FUNDS IS STILL SUBJECT
25 TO CIRM'S REGULATIONS. SO ALL THE ALLOWABLE COSTS

BARRISTERS' REPORTING SERVICE

1 AND THE OVERHEAD, FACILITIES AND INDIRECT
2 REQUIREMENTS, THEY WOULD CERTIFY THAT THE FUNDS
3 WOULD BE USED SUBJECT TO THOSE REQUIREMENTS.

4 UNIDENTIFIED SPEAKER: WHAT WOULD BE A
5 TYPICAL EXAMPLE OF WHERE A RESEARCHER WOULD WANT TO
6 PAY BACK CO-FUNDING OR BUY IT DOWN TO A MINIMUM? IF
7 I UNDERSTOOD GABE CORRECTLY, WE USE LEFTOVER MONEY
8 TO GO BACK TO BUY DOWN CO-FUNDING TO WHATEVER THE
9 MINIMUM CO-FUNDING AMOUNT WAS. SO IF IT WAS MORE
10 THAN THAT, BUY-DOWN TO WHAT THE MINIMUM PLEDGED WAS.
11 WHAT WOULD BE THE MOTIVATION FOR DOING THAT? IS IT
12 SOMETHING THAT YOU WOULD TAKE OFF THE TABLE? I
13 ASSUME THESE ARE NOT LOANS, COPAYS ARE NOT LOANS, SO
14 IT WOULDN'T BE PAYING OFF THE LOAN. THAT MAKE
15 SENSE, RANDY?

16 DR. MILLS: I'VE NEVER HEARD OF THAT
17 VERSION BEFORE. I GUESS WHAT WOULD HAVE HAD TO HAVE
18 HAPPENED IN THAT SCENARIO IS THEY ENDED UP WITH
19 MONEY LEFT OVER BECAUSE THEY PUT IN MORE MONEY THAN
20 THEY WERE SUPPOSED TO. AND SO THEY COULD JUST TAKE
21 THAT MONEY BACK OUT. IF IT WAS -- IF THE COMPANY
22 WAS SUPPOSED TO PUT IN, IF IT'S A COMPANY, WAS
23 SUPPOSED TO PUT IN \$4 MILLION AND WE PUT IN \$6
24 MILLION, AND AT THE END OF THE GRANT THERE WERE
25 SAVINGS LEFT OVER, BUT THEY HAD ACTUALLY PUT IN 4.5

BARRISTERS' REPORTING SERVICE

1 MILLION, IF THERE'S \$300,000 LEFT, THEY CAN GET IT
2 BECAUSE THEY'VE OVERSPENT. BUT IT CAN'T THROW IT
3 OUT OF WHAT AGREED UPON...

4 MR. THOMPSON: SO ANY MORE QUESTIONS ON
5 THAT? THOSE ARE THE HIGH LEVEL FEATURES. SO,
6 AGAIN, THESE INTERIM REGS, WE'RE ASKING INPUT. WE
7 GO TO THE ICOC WITH THESE REGS AT THE NEXT MEETING.
8 IF THEY'RE APPROVED, THEN THEY OPEN THE RULEMAKING
9 PROCESS. THIS IS OUR FIRST PASS AT THESE
10 REGULATIONS, SO WE WILL HAVE OTHER OPPORTUNITIES TO
11 RECEIVE INPUT THROUGHOUT THIS PROCESS. SO WE HAVE
12 THE 270-DAY AUTHORITY TO ADOPT INTERIM REGULATIONS,
13 START THE RULEMAKING PROCESS; BUT THEN ACROSS THE
14 NEXT X NUMBER OF MONTHS, CALL IT NINE MONTHS OR SO,
15 WE CAN CONTINUE TO WORK ON THESE REGS. SO THAT
16 GIVES US SOME FLEXIBILITY THERE.

17 CHAIRMAN SHEEHY: ARE THERE ANY QUESTIONS
18 FROM ANY MEMBERS OF THE SUBCOMMITTEE?

19 DR. FRIEDMAN: SO THIS IS MIKE FRIEDMAN.
20 CAN I ASK JUST A COUPLE OF QUESTIONS, PLEASE, FOR
21 CLARIFICATION?

22 CHAIRMAN SHEEHY: SURE.

23 DR. FRIEDMAN: ONE IS, AND THIS MAY BE A
24 LEVEL OF DETAIL THAT WE JUST HAVEN'T WORKED OUT YET,
25 FOR SUSPENSION EVENTS, WILL THAT INFORMATION BE

BARRISTERS' REPORTING SERVICE

1 BROUGHT BACK TO THE BOARD, OR WILL THAT JUST BE
2 HANDLED ADMINISTRATIVELY?

3 DR. MILLS: SO, MIKE, THIS IS RANDY. SO
4 IT REALLY IS GOING TO DEPEND ON THE SEVERITY OF THE
5 SUSPENSION EVENT AND HOW QUICKLY WE GET IT REMEDIED.
6 I ACTUALLY THINK IT'S PROBABLY NOT A BAD IDEA TO
7 REPORT BACK TO THE BOARD THE SUSPENSION EVENTS THAT
8 WE RUN INTO, BUT IT CERTAINLY COULD BE THAT A
9 SUSPENSION EVENT COMES AND IS RESOLVED BETWEEN NOW
10 AND THE NEXT BOARD MEETING. AN EXAMPLE WOULD BE IF
11 A TRIAL RAN INTO -- WAS PUT ON CLINICAL HOLD, THAT
12 WOULD BE A SUSPENSION EVENT FOR US, BUT CLINICAL
13 HOLDS CAN BE RESOLVED IN DAYS IF IT ENDS UP BEING
14 ACTUALLY A MINOR ISSUE. SO IN WHICH CASE WE WOULD
15 GO BACK AND REPORT TO THE BOARD THERE WAS A
16 SUSPENSION EVENT, THEY TRIGGERED IT, THEY RESOLVED
17 IT, AND HERE WE ARE.

18 CERTAINLY THE SUSPENSION EVENTS THAT LEAD
19 TO TERMINATION WOULD COME BACK TO THE BOARD IN A
20 TIMELY FASHION.

21 DR. FRIEDMAN: THAT SEEMS VERY LOGICAL TO
22 ME BECAUSE I CAN IMAGINE -- WELL, IT SOUNDS VERY
23 REASONABLE WHAT YOU'RE SAYING. SO THAT PART IS JUST
24 FINE.

25 AND I GUESS I'M GENERALLY SUPPORTIVE OF

BARRISTERS' REPORTING SERVICE

1 THE IDEA OF, IF THERE'S EXCESS FUNDS AT THE END OF
2 THE PROJECT AND YOU'VE MET ALL THE MILESTONES, OF
3 GIVING SOME OF THE MONEY BACK TO THE INSTITUTION IF
4 THEY HAVE SPENT MORE THAN THEY ANTICIPATED, BUT I
5 SUSPECT THAT THIS IS GOING TO BE A VERY DIFFICULT
6 THING TO ACTUALLY ADJUDICATE AND ENFORCE. AND THE
7 REASON IS OVER THE COURSE OF A COUPLE OF YEARS,
8 INSTITUTIONAL COSTS GO UP, EVERYTHING FROM THE COST
9 OF LABORATORY SUPPLIES TO THE MINIMUM WAGE FOR
10 TECHNICIANS AND ALL SORTS OF THINGS. AND SO I THINK
11 ANY INSTITUTION MAY BE ABLE TO DEMONSTRATE THAT IT
12 SPENT MORE THAN IT ANTICIPATED AT THE BEGINNING.
13 AND I THINK IT'S GOING TO BE A LITTLE COMPLICATED,
14 BUT IT DOESN'T MAKE ME WANT TO VOTE AGAINST IT. IT
15 SIMPLY WANTS ME TO WEIGH -- I THINK THIS IS
16 SOMETHING THAT'S VERY REASONABLE IN THEORY AND MAYBE
17 RATHER MORE DIFFICULT TO IMPLEMENT.

18 DR. MILLS: SO, MICHAEL, THE WAY WE'RE
19 TRYING TO RECONCILE THOSE -- HOW WE -- WHAT WE'RE
20 TRYING TO DO HERE IS USE ECONOMICS TO DRIVE THE
21 CORRECT BEHAVIOR. AND THE CORRECT BEHAVIOR IS WE
22 WANT THINGS DONE QUICKLY AND CORRECTLY, AND WE DON'T
23 WANT TO PENALIZE PEOPLE FOR DOING THAT. SO THAT
24 KIND OF MAY SOUND STRANGE; BUT IN THE PAST, IF YOU
25 GOT DONE WITH YOUR AWARD EARLY, YOU WOULD FORFEIT

BARRISTERS' REPORTING SERVICE

1 THE OVERHEAD YOU WOULD GET WHILE THAT AWARD WAS
2 ACTIVE. AND SO WE WERE NOT INCENTIVIZING -- WE WERE
3 INCENTIVIZING PEOPLE TO HAVE THEIR PROGRAMS,
4 FRANKLY, TAKE FROM AN ECONOMIC STANDPOINT AS LONG AS
5 THEY COULD. AND SO THE WAY WE SORT OF THE SWITCHED
6 THE PARADIGM IS ON THE VERY FRONT END, EVEN BEFORE,
7 AND THIS IS ACTUALLY JEFF'S IDEA, EVEN BEFORE THE
8 GWG REVIEWS THE MERITS OF THE AWARD, WE LOOK AND SEE
9 WHAT, IN THIS CASE A CLINICAL TRIAL OR THE LIKE, WE
10 LOOK AND FIGURE OUT HOW MUCH THAT SHOULD COST, NOT
11 JUST HOW MUCH THEY'RE PROPOSING IT COST, BUT HOW
12 MUCH THAT TRIAL IS WORTH IN MARKET TERMS. IF WE
13 LIKED IT AND WANTED TO BUY A COMPETITIVE VERSION OF
14 THAT, WHAT ARE THE MARKET RATES FOR THAT?

15 AND THEN WE SAY -- AND SO WE DO THIS
16 BUDGET REVIEW AND WE SAY, OKAY, THEY SAY IT'S \$13
17 MILLION AND WE'VE HAD THIS EXTERNALLY VERIFIED THAT
18 THE ACTUAL VALUE OF THIS THING IS \$13 MILLION.
19 WELL, WE'RE BUYING A PRODUCT WITH MILESTONES AND
20 WITH THINGS THAT IT HAS TO BE 60 PATIENTS AND IT'S
21 GOT TO DO DA-DA-DA-DA, WHATEVER THE VARIOUS
22 COMPONENTS OF IT ARE, AND WE KNOW THAT A FAIR PRICE,
23 IF WE COULD JUST BUY THAT NOW, A FAIR PRICE FOR THAT
24 IS \$13 MILLION. SO IF THEY CAN GET IT DONE MORE
25 QUICKLY AND THEREFORE HAVE SOME SAVINGS ASSOCIATED

BARRISTERS' REPORTING SERVICE

1 WITH THAT, LET'S SAY THEY GET IT DONE AT 12.5
2 MILLION, WE WANT TO MAKE SURE THAT THEY'RE
3 INCENTIVIZED TO DO THAT PROVIDED THEY TAKE WHATEVER
4 SAVINGS THEY HAVE AND THEY REINVEST IT INTO
5 CIRM-TYPE MISSIONS, BUT WITHOUT US DICTATING EXACTLY
6 WHAT IT IS, BUT JUST SOMETHING OVERALL THAT EITHER
7 SERVES TO FURTHER ADVANCE THEIR PROGRAM OR OTHER
8 PROGRAMS.

9 SO KIND OF A REALLY IMPORTANT CONCEPT HERE
10 IS THAT IF THEY COMPLETE THE PROJECT AS PROPOSED, WE
11 ARE ON THE FRONT END HAPPY WITH THE PRICE THAT WE
12 PAID FOR A COMPLETED PROJECT. AND IF THEY WERE ABLE
13 TO GET THAT DONE A LITTLE BIT MORE EFFICIENTLY THAN
14 WE ANTICIPATED OR QUICKER, THEN WE DON'T WANT TO
15 PENALIZE THEM FOR IT.

16 DR. FRIEDMAN: I DO UNDERSTAND. THANK
17 YOU.

18 DR. MILLS: OKAY.

19 CHAIRMAN SHEEHY: ARE THERE OTHER
20 QUESTIONS FROM MEMBERS ON THE PHONE?

21 DR. VUORI: THIS IS KRISTINA. I WANTED TO
22 PULL UP A LITTLE BIT ON THE CLINICAL ADVISORY PANELS
23 BEING INTRODUCED IN THIS CONTEXT. AND I THINK IT'S
24 ABSOLUTELY A REALLY GREAT IDEA TO HAVE THESE
25 EXPERTS, THESE OUTSIDE FOLKS, WHO CAN PROVIDE REALLY

BARRISTERS' REPORTING SERVICE

1 SPECIFIC INSIGHTS. MY QUESTION IS MAYBE AS THE WAY
2 OF AN EXAMPLE IS THAT IN THE BEGINNING OF THIS WHOLE
3 PROCESS, THE PROJECT IS FUNDED AND IT'S BASED ON THE
4 IDEAS OF THE GRANTEE AND THE FEEDBACK OF THE GRANTS
5 WORKING GROUP, BUT DURING THE COURSE OF A CLINICAL
6 PROJECT, MANY THINGS MAY CHANGE DRASTICALLY AND
7 ESPECIALLY THE CLINICAL ADVISORY PANEL MAY END UP
8 RECOMMENDING DOING VERY DIFFERENT THINGS THAN MIGHT
9 HAVE BEEN IN THE ORIGINAL PLAN. WHAT IS THE
10 MECHANISM OF THE RESOLUTION AS TO WHO EVENTUALLY
11 DECIDES WHAT'S TO BE DONE? IS IT CIRM? IS IT THE
12 PRESIDENT? DO THINGS GO BACK TO THE GRANTS WORKING
13 GROUP? WHAT IS THE ROLE OF THE BOARD AS WELL WHEN
14 WE HAVE SEEN CERTAIN THINGS BEING FUNDED AND
15 ADVISORY PANELS, SOME SUCH AS THAT, WHO CAN PROVIDE
16 SUGGESTIONS THAT ARE COMPLETELY JUSTIFIED, BUT MAYBE
17 NOT ANTICIPATED IN THE BEGINNING. HOW MUCH IS THERE
18 FLEXIBILITY TO CHANGE THINGS ON THE FLY, OR HOW DO
19 YOU DEAL WITH THAT?

20 DR. MILLS: SO THE CHARGE OF THE CLINICAL
21 ADVISORY PANEL IS TO ACCOMPLISH, TO BEST ACCOMPLISH
22 THE PROGRAM AS APPROVED BY THE BOARD AND CONTRACTED
23 BY CIRM. AND SO THEY ARE ASSEMBLED -- THE ASSEMBLY
24 OF THAT STARTS REALLY LIKE LITERALLY THE DAY THAT
25 THE BOARD APPROVES AND SHOULD BE IN PLACE BY THE

BARRISTERS' REPORTING SERVICE

1 TIME CONTRACTING IS COMPLETE SO THAT THEY ARE --
2 WHAT WE WERE TRYING TO DO IS TAKE FULL ADVANTAGE OF
3 THE ADVICE THAT WE FOUND WE COULD GET OUT OF CDAP;
4 BUT INSTEAD OF HAVING THAT ADVICE A YEAR INTO A
5 TRIAL WHEN IT'S VERY DIFFICULT TO MAKE COURSE
6 CORRECTION, WE WANTED IT FROM THE OUTSET. SO THAT'S
7 WHERE THE CONCEPT OF THE CAP'S COME FROM. THEY'RE
8 LIKE A CDAP, BUT THEY MEET RIGHT AT THE BEGINNING.
9 THEY'RE DURABLE, THEY MEET QUARTERLY, AND THEY STAY
10 WITH IT.

11 THEIR CHARGE IS NOT TO BASICALLY HAVE
12 REIGN OVER -- CHANGE THE PROGRAMS FROM WHAT THE
13 BOARD APPROVED. OUR HOPE IS THE PROGRAMS, BECAUSE
14 WE HAVE THIS ITERATIVE PROCESS THAT ALLOWS FOR
15 SOMETHING LESS THAN AN EXCEPTIONAL OR DARE I USE THE
16 WORD PERFECT APPLICATION TO BE AMENDED AND MADE
17 BETTER, THAT OUR PROJECTS LAUNCH WITH A HIGHER
18 QUALITY AND REQUIRE LESS COURSE CORRECTION OUT OF
19 THE GATE. AND SO THE INTENT THERE IS TO MAKE SURE
20 THAT THE PRODUCT THE BOARD SEES IS THE PRODUCT WE'RE
21 GOING TO CONTINUE WITH UNTIL SOMETHING HAPPENS, NOT
22 LIKE WHERE WE WOULD FUND -- IF WE FUND AT 70 IN THE
23 PAST, THAT MIGHT BE SOMETHING WHERE A CDAP PANEL
24 WOULD BE MAKING RECOMMENDATIONS ON CHANGING THE
25 FIRST TIME CDAP MET. HERE IF WE FUND A 95 THAT THE

BARRISTERS' REPORTING SERVICE

1 BOARD'S LOOKED AT AND WE'RE COMFORTABLE WITH IT,
2 THAT'S SOMETHING THAT WE WOULD ANTICIPATE WOULDN'T
3 NEED TO BE CHANGED UNTIL SOMETHING EXCEPTIONAL
4 HAPPENS.

5 THE CLINICAL ADVISORY PANEL HAS THE
6 ABILITY TO WORK WITH THE INVESTIGATOR TO COME UP
7 WITH THE BEST PLANS POSSIBLE. THEY HAVE THE ABILITY
8 TO BRING IN RESOURCES FROM CIRM OR RESOURCES
9 EXTERNAL TO CIRM TO HELP MOVE THE PROGRAM ALONG.
10 THEY DO NOT HAVE THE AUTHORITY TO MODIFY THE
11 CONTRACT THOUGH. SO THEY CANNOT CHANGE THE SCOPE.
12 THEY CANNOT CHANGE ANY MATERIAL TERMS OF THE
13 CONTRACT ON THEIR OWN. SIMILARLY, THEY CANNOT
14 ADJUDICATE SUSPENSION EVENTS OR TERMINATION EVENTS.
15 AND SO THAT WOULD BE SOMETHING THAT WOULD REQUIRE
16 COMING BACK INTO CIRM, AND DEPENDING ON WHAT THE
17 ISSUE WOULD BE, TO EITHER ME OR THE GWG OR A
18 COMBINATION OF THOSE.

19 DR. VUORI: GOOD. THANKS.

20 CHAIRMAN SHEEHY: ACTUALLY THAT KIND OF
21 RAISES A COUPLE OF QUESTIONS THAT I HAD SINCE WE'RE
22 ON THE SUBJECT.

23 SO THE CDAP, WHERE DOES THAT EXIST? IS
24 THAT IN THE GAP? IS THAT IN BYLAWS? IS THIS
25 ANYTHING THAT THE BOARD HAS EVER APPROVED?

BARRISTERS' REPORTING SERVICE

1 MR. HARRISON: NO. THE CLINICAL ADVISORY
2 PANELS WERE REFERENCED IN THE CONCEPT PROPOSAL FOR
3 THE DISEASE TEAM PROGRAMS, BUT THAT'S THE ONLY PLACE
4 THAT THERE WAS EVER ANY FORMAL MENTION OF THEM. SO
5 THEY WERE INFORMAL BODIES ESTABLISHED BY THE CIRM
6 TEAM.

7 DR. MILLS: CDAP IS OVER.

8 CHAIRMAN SHEEHY: OKAY. SO HOW ARE
9 CURRENT PROJECTS NOW BEING -- WHAT IS IT GOING
10 FORWARD FOR PROJECTS?

11 DR. MILLS: SO WHAT WE'VE DONE WITH OUR
12 CURRENT PROGRAMS THAT WOULD OTHERWISE BE SUBJECT TO
13 CDAP IS WE'VE PUT THEM ON A SCHEDULE, BASICALLY
14 PRIORITIZED THEM. SO THERE ARE SOME PROGRAMS THAT
15 END PRIOR TO OUR NEXT CDAP MEETING ANYWAY AND
16 THEY'RE SO FAR ALONG, THEY'RE NOT BEING CONVERTED.
17 WE'RE TAKING IN HIERARCHY AND WE HAVE A COUPLE OF
18 DIFFERENT PARAMETERS. OUR PROGRAMS WITH THE MOST
19 LIFE ON THEM WERE THE ONES THAT FRANKLY COULD USE
20 THE HELP, AND WE'RE CREATING CAP'S FOR THOSE TOO.
21 SO IT'S EITHER GOING TO FINISH BEFORE WE WOULD GET
22 AROUND TO FORMING A CAP OR A CAP WILL TAKE THE PLACE
23 OF ITS CDAP OVERSIGHT.

24 CHAIRMAN SHEEHY: SO IN THIS DOCUMENT, IT
25 WOULD HELP ME IF THE GAP MEMBERSHIP WAS MORE

BARRISTERS' REPORTING SERVICE

1 SPECIFIED.

2 MS. BONNEVILLE: CAP.

3 CHAIRMAN SHEEHY: CAP. THE CAP
4 MEMBERSHIP, MY UNDERSTANDING AS A PATIENT ADVOCATE,
5 THERE'S A DESIRE TO HAVE A PATIENT ADVOCATE, BUT
6 THAT'S NOT IN THIS PRESENT ITERATION.

7 MR. HARRISON: CORRECT. SO THE MEMBERSHIP
8 OF THE CAP IS SPECIFIED IN DRAFT BYLAWS THAT WE'VE
9 PREPARED FOR THE CAP WHICH WE WILL DISTRIBUTE TO
10 MEMBERS OF THE SCIENCE SUBCOMMITTEE AND THE BOARD
11 FOR YOU TO REVIEW. IT'S NOT INCLUDED IN THE GRANTS
12 ADMINISTRATION POLICY IN PART BECAUSE THESE ARE
13 BODIES THAT WILL BE ESTABLISHED BY THE PRESIDENT,
14 APPOINTED BY THE PRESIDENT, NOT BODIES CREATED BY
15 THE BOARD ITSELF. AND THE SIGNIFICANCE OF THAT IS
16 THAT IF THEY WERE CREATED BY THE BOARD, THEY WOULD
17 BE SUBJECT TO BAGLEY-KEENE RULES. WE'D HAVE TO
18 NOTICE THE MEETINGS OF THE CAP'S, ETC. AND THE
19 BOARD WILL HAVE FULL VISIBILITY INTO WHAT THE CAP'S
20 DO, BUT IT'S NOT A FORMAL PART OF WHAT WE'RE ASKING
21 YOU TO APPROVE.

22 CHAIRMAN SHEEHY: GREAT. AND THEN JUST
23 ONE MORE QUESTION BECAUSE IT CAME UP. THE NEW
24 OPTION FOR THE GRANTS WORKING GROUP TO RECOMMEND,
25 WHEN I LOOKED IN HERE, I SEE THE OLD TIER II

BARRISTERS' REPORTING SERVICE

1 DESIGNATION. I THOUGHT I SAW -- WHEN I LOOK AT TIER
2 II, I'M AGING, BUT I HAVE PROVISIONALLY RECOMMENDED
3 FOR FUNDING. AND THAT IS DIFFERENT FROM WHAT WE'RE
4 TALKING ABOUT.

5 UNIDENTIFIED SPEAKER: THAT DOESN'T SOUND
6 RIGHT.

7 CHAIRMAN SHEEHY: YEAH. SO WE SHOULD
8 MAYBE CHANGE THAT BACK AS WE ADOPT A MOTION ABOUT
9 TIER II IN THE APPLICATION REVIEW ON PAGE 15. PART
10 D, NO. 2 ACTUALLY REFLECTS THAT TIER II WILL BE
11 GOING FORTH.

12 MR. HARRISON: SO WE PERHAPS DIDN'T
13 CAPTURE IT IN THE TITLE. IN THE TEXT OF THAT
14 LANGUAGE, WE REFER TO THE FACT THAT THE APPLICATIONS
15 MAY REQUIRE FURTHER CONSIDERATION BY THE APPLICATION
16 REVIEW SUBCOMMITTEE, AND THE GWG CAN CHANGE THE
17 DESIGNATION, BUT WE'LL CLARIFY IT MORE.

18 DR. MILLS: I DON'T EVEN WANT TO USE THE
19 WORD "TIER II" OR THE TERM "TIER II" BECAUSE IT'S
20 REALLY DIFFERENT, BUT THE SECOND TIER, BUCKET, OR
21 WHATEVER YOU WANT TO CALL IT IS NOT A RECOMMENDATION
22 FOR FUNDING. IN FACT, IT'S A RECOMMENDATION NOT FOR
23 FUNDING. IT'S A RECOMMENDATION FOR AMENDING.

24 CHAIRMAN SHEEHY: AMENDING AND REAPPLYING.
25 OKAY. SORRY THAT I TOOK UP ALL THAT TIME, BUT ARE

BARRISTERS' REPORTING SERVICE

1 THERE OTHER QUESTIONS FROM OTHER MEMBERS ON THE
2 PHONE?

3 (NO RESPONSE.)

4 WE WILL THEN, IF THERE'S NO OTHER
5 QUESTIONS, THEN PERHAPS A MOTION TO ADOPT.

6 DR. FRIEDMAN: SO MOVED.

7 CHAIRMAN SHEEHY: AND DR. FRIEDMAN MADE
8 THE MOTION. DO I HAVE A SECOND?

9 DR. VUORI: SECOND.

10 CHAIRMAN SHEEHY: SECOND FROM DR. VUORI.
11 AND THEN I THINK, MARIA, COULD YOU CALL THE ROLL.

12 MS. BONNEVILLE: MICHAEL FRIEDMAN.

13 DR. FRIEDMAN: YES.

14 MS. BONNEVILLE: DAVID HIGGINS.

15 DR. HIGGINS: YES.

16 MS. BONNEVILLE: BURT LUBIN.

17 DR. LUBIN: YES.

18 MS. BONNEVILLE: SHLOMO MELMED. JEFF
19 SHEEHY.

20 CHAIRMAN SHEEHY: YES.

21 MS. BONNEVILLE: OS STEWARD.

22 DR. STEWARD: YES.

23 MS. BONNEVILLE: JONATHAN THOMAS.

24 CHAIRMAN THOMAS: YES.

25 MS. BONNEVILLE: KRISTINA VUORI.

BARRISTERS' REPORTING SERVICE

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

DR. VUORI: YES.

MS. BONNEVILLE: AND, DR. MELMED, ARE YOU
ON THE LINE?

MR. HARRISON: MOTION CARRIES.

CHAIRMAN SHEEHY: GREAT. WELL, THANK
YOU -- UNLESS SOMEONE HAS SOMETHING ELSE, I THINK
WE'RE DONE WITH THIS MEETING. THANK YOU FOR YOUR
TIME.

(THE MEETING WAS THEN CONCLUDED AT 4:33
P.M.)

REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE TELEPHONIC PROCEEDINGS BEFORE THE SCIENCE SUBCOMMITTEE OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON JANUARY 20, 2015, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

BETH C. DRAIN, CSR 7152
BARRISTERS' REPORTING SERVICE
160 S. OLD SPRINGS ROAD
SUITE 270
ANAHEIM, CALIFORNIA
(714) 444-4100