

BEFORE THE
CITIZENS FINANCIAL ACCOUNTABILITY
OVERSIGHT COMMITTEE

ORGANIZED PURSUANT TO THE
CALIFORNIA STEM CELL RESEARCH AND CURES ACT
REGULAR MEETING

DATE: THURSDAY, OCTOBER 27, 2016

TIME: 9 A.M.

LOCATION: SOUTHERN CALIFORNIA ASSOCIATION OF
GOVERNMENTS BOARD ROOM
818 WEST 7TH STREET
12TH FLOOR
LOS ANGELES, CA 90017

BRS FILE NO.: 99051

BARRISTERS' REPORTING SERVICE

I N D E X

OPEN SESSION:	PAGE NO.
CALL TO ORDER AND ROLL CALL	3
OPENING STATEMENT	3
ACTION ITEMS:	
ADOPT MINUTES OF THE OCTOBER 1, 2015, CFAOC MEETING	NOT HEARD
INFORMATION ITEMS:	
PRESENTATION OF THE 2014-15 INDEPENDENT FINANCIAL AUDIT BY MACIAS, GINI & O'CONNELL	6
THE STATE CONTROLLER'S OFFICE AUDIT REVIEW REPORT	9
STATUS UPDATE OF CIRM'S UPDATE OF GRANTS AWARDED AND STRATEGIC PLAN	10
FINANCIAL PERFORMANCE, CURRENT BUDGET	53
CLINICAL PORTFOLIO REVIEW	65
PUBLIC COMMENT	NONE
BOARD MEMBER TIME	NONE
ADJOURNMENT	81

BARRISTERS' REPORTING SERVICE

1 LOS ANGELES, CALIFORNIA; THURSDAY, OCTOBER 27, 2016

2 9 A.M.

3

4 CHAIRPERSON YEE: I THINK WE'LL GO AHEAD
5 AND GET STARTED. WE ARE AWAITING DR. LIPSON'S
6 ARRIVAL, BUT WE CAN BEGIN. LET ME BEGIN BY FIRST
7 SAYING GOOD MORNING. MY NAME IS STATE CONTROLLER
8 BETTY YEE, AND HAPPY TO SERVE AS CHAIR OF THE
9 OVERSIGHT COMMITTEE.

10 LET ME HAVE DEPUTY CONTROLLER ALLAN LAFASO
11 PLEASE CALL THE ROLL.

12 MR. LAFASO: THANK YOU, MADAM CONTROLLER.
13 DR. GURBINDER SEDANA.

14 DR. SADANA: PRESENT.

15 MR. LAFASO: DR. MICHAEL QUICK.

16 DR. QUICK: PRESENT.

17 MR. LAFASO: DR. LOREN LIPSON. NOT HERE
18 YET. DR. TED LOVE. NOT HERE. MR. JIM LOTT. NOT
19 HERE. AND CONTROLLER BETTY YEE.

20 CHAIRPERSON YEE: HERE.

21 OKAY. WE WILL CONVENE AS A SUBCOMMITTEE.
22 ABSENT A QUORUM, WE WILL NOT BE TAKING ANY ACTION,
23 BUT WHY DON'T WE BEGIN.

24 THANK YOU FOR CONVENING THIS MORNING.
25 WANT TO WELCOME DR. QUICK AND DR. SEDANA. AND JUST

BARRISTERS' REPORTING SERVICE

1 BY WAY OF BACKGROUND, PROP 71 TASKED THE STATE
2 CONTROLLER TO CONVENE THIS OVERSIGHT COMMITTEE,
3 CONSISTING OF APPOINTEES FROM THE LEGISLATIVE
4 LEADERSHIP AND OTHER STATE ENTITIES, TO MEET AT
5 LEAST ONCE A YEAR TO EXAMINE FINANCES OF OUR STATE'S
6 INNOVATIVE TAXPAYER-FUNDED STEM CELL AGENCY, THE
7 CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE,
8 OTHERWISE KNOWN AS CIRM.

9 OVER THE LAST TEN YEARS THE COMMITTEE HAS
10 WITNESSED SOME OF THE MAJOR ISSUES TO COME BEFORE
11 CIRM, INCLUDING ESTABLISHING THE AGENCY, ITS IMPACT
12 ON DEVELOPING STEM CELL RESEARCH AROUND THE WORLD,
13 AND EVOLUTION OF THE ORGANIZATION ITSELF.

14 LAST YEAR CIRM WAS EMBARKING ON ITS REBOOT
15 KNOWN AS CIRM 2.0. THIS COMMITTEE HEARD OF MANY OF
16 THE MAJOR CHANGES TAKING HOLD AT THE AGENCY. SINCE
17 THEN CIRM'S NEW STRATEGIC PLAN HAS BEEN ADOPTED AND
18 IS TRANSLATING CIRM'S CONTINUED IMPACT ON STEM
19 RESEARCH IN CALIFORNIA, AN INCREASINGLY PROMISING
20 AREA OF MEDICAL RESEARCH.

21 CIRM IS NOW FUNDING 22 NEW THERAPIES AND
22 CLINICAL TRIALS WITH AN ADDITIONAL 45 OR SO
23 THERAPIES IN THE RESEARCH PIPELINE. TWELVE YEARS
24 INTO THE LIFE OF PROP 71, WE ARE SEEING A RETURN ON
25 THE TAXPAYER'S INVESTMENT. IT IS IMPORTANT THAT THE

BARRISTERS' REPORTING SERVICE

1 PUBLIC KNOWS WHAT IT IS RECEIVING FROM ITS
2 INVESTMENT, AND EQUALLY IMPORTANT THE PUBLIC NEEDS
3 TO KNOW WHAT STRATEGIES HAVE WORKED, THE EXTENT OF
4 WHAT IT HAS GAINED OVER THE LIFE OF PROP 71, FOR
5 EXAMPLE, THE MEASURE OF WORKFORCE DEVELOPMENT OR
6 OTHER INFRASTRUCTURE, AND ITS OPTIONS FOR STEM CELL
7 INNOVATION INTO THE FUTURE.

8 TODAY I EXPECT THAT THE COMMITTEE WILL
9 LEARN MORE ABOUT THE CURRENT STATE OF CIRM'S
10 ACTIVITIES, IMPLEMENTING ITS NEW STRATEGIC PLAN,
11 FOCUSING ON FUNDING PROGRAMS, AND INITIATIVES.

12 I HOPE WE WILL LEARN MORE ABOUT HOW CIRM
13 IS IMPACTING THE STEM CELL RESEARCH ENVIRONMENT MORE
14 BROADLY, ITS PARTNERSHIPS, THE EVOLVING ROLE OF
15 PATIENTS AND THE REGULATORY PROCESS. AS MORE
16 TREATMENTS GET CLOSER TO MARKET AND AVAILABILITY TO
17 GREATER NUMBERS OF PATIENTS, THESE ISSUES ARE
18 INCREASINGLY IMPORTANT FACTORS FOR EVALUATING CIRM'S
19 IMPACT ON THE CURRENT STATE OF STEM CELL RESEARCH.
20 AND LET ME JUST ADD THAT THIS HAS JUST BEEN REALLY
21 AN EXCITING PART OF MY ROLE AS STATE CONTROLLER TO
22 SEE THIS TREMENDOUS AREA OF INNOVATION THAT WILL
23 HAVE JUST VERY PROFOUND IMPACTS.

24 AND I, AGAIN, WANT TO WELCOME DR. QUICK
25 AND DR. SEDANA.

BARRISTERS' REPORTING SERVICE

1 BEFORE WE GET STARTED INTO THE AGENDA
2 WOULD WELCOME ANY OPENING COMMENTS BY EITHER MEMBER.

3 DR. SADANA: JUST THANKING YOU FOR
4 CHAIRING THIS FOR OUR STATE AND SHOWING US
5 LEADERSHIP IN MAKING THIS HAPPEN.

6 CHAIRPERSON YEE: THANK YOU.

7 DR. QUICK: YES. THANK YOU SO MUCH FOR
8 YOUR LEADERSHIP ON THIS. PROP 71 HAS BEEN
9 TRANSFORMATIVE FOR THE STATE OF CALIFORNIA, AND IT'S
10 AN HONOR TO BE A MEMBER OF THIS COMMITTEE. THANK
11 YOU.

12 CHAIRPERSON YEE: THANK YOU. THANK YOU,
13 DR. QUICK.

14 ALL RIGHT. WHY DON'T WE MOVE, THEN, TO
15 ITEM NO. 5. WE WILL PASS ON ITEM NO. 4, THE MINUTES
16 OF THE OCTOBER 1ST, 2015, MEETING. IF WE COULD HAVE
17 THE PRESENTATION OF THE 2014-15 INDEPENDENT
18 FINANCIAL AUDIT BY MACIAS, GINI & O'CONNELL. AND I
19 BELIEVE CRAIG CONNER IS HERE. GOOD MORNING.

20 MR. CONNER: GOOD MORNING, MEMBERS OF THE
21 COMMITTEE. MY NAME IS CRAIG CONNER. I'M A SENIOR
22 MANAGER AT MGO, AND I WAS ACTUALLY THE MANAGER ON
23 THE CIRM ENGAGEMENT FOR THE FINANCIAL STATEMENTS
24 THAT WE'RE GOING TO DISCUSS THIS MORNING.

25 BEFORE I GET INTO MY PRESENTATION, I JUST

BARRISTERS' REPORTING SERVICE

1 WANT TO TAKE A MOMENT TO THANK THE COMMITTEE FOR THE
2 OPPORTUNITY TO LET US PRESENT THE RESULTS OF OUR
3 WORK, AND I ALSO WANT TO THANK THE STAFF AND
4 MANAGEMENT AT CIRM FOR ALL THE ASSISTANCE IN HELPING
5 US WITH OUR AUDIT.

6 SO WE WERE ENGAGED TO PERFORM AN AUDIT OF
7 CIRM'S FINANCIAL STATEMENTS OF THEIR GOVERNMENTAL
8 ACTIVITIES AND THE MAJOR FUND ALSO KNOWN AS THE STEM
9 CELL FUND FOR THE FISCAL YEAR ENDED JUNE 30, 2015.
10 THE PURPOSE OF OUR AUDIT IS TO EXPRESS AN OPINION ON
11 THOSE FINANCIAL STATEMENTS FOR THE YEAR THEN ENDED.

12 AND AS A PART OF OUR AUDIT, WE ISSUED
13 ACTUALLY THREE REPORTS, TWO OF WHICH ARE CONTAINED
14 IN THE FINANCIAL STATEMENTS, AND THEN THE SECOND ONE
15 IS AN INDEPENDENT REPORT WE ISSUE TO THE INDEPENDENT
16 CITIZENS OVERSIGHT COMMITTEE OR ICOC, AND THAT
17 CONTAINS WHAT'S CALLED OUR REQUIRED COMMUNICATIONS.
18 JUST AT THE END OF OUR AUDIT, WE'RE REQUIRED TO
19 COMMUNICATE CERTAIN MATTERS TO THOSE CHARGED WITH
20 GOVERNANCE. I WON'T TOUCH TOO MUCH ON THAT REPORT
21 THIS MORNING AS THERE WAS NOTHING REALLY THAT WAS
22 UNORDINARY OR REALLY NOT OF CONCERN. EVERYTHING WAS
23 PRETTY STANDARD.

24 OKAY. SO GET TO THE RESULTS OF OUR
25 FINANCIAL STATEMENT AUDIT IDENTIFIED ON PAGE 3 OF

BARRISTERS' REPORTING SERVICE

1 OUR INDEPENDENT AUDITOR'S REPORT. WE ISSUED OUR
2 OPINION ON CIRM'S FINANCIAL STATEMENTS ON OCTOBER
3 15, 2015. AND WE ARE PLEASED TO REPORT THAT WE
4 OBTAINED SUFFICIENT AND APPROPRIATE AUDIT EVIDENCE
5 WHICH ALLOWS US TO RENDER WHAT'S CALLED AN
6 UNMODIFIED OPINION. AN UNMODIFIED OPINION IS THE
7 HIGHEST LEVEL OF ASSURANCE THAT AN INDEPENDENT
8 AUDITOR CAN GIVE AN ORGANIZATION REGARDING THEIR
9 FINANCIAL STATEMENTS.

10 AND THEN THE LAST REPORT IS ON PAGES 24
11 AND 25 OF THE FINANCIAL STATEMENTS. AND THIS IS
12 WHAT WE CALL THE YELLOW BOOK REPORT. THIS REPORT IS
13 FOR WHEN WE PERFORM AN AUDIT IN ACCORDANCE WITH THE
14 GOVERNMENT AUDITING STANDARDS. WE ARE REQUIRED TO
15 REVIEW THE INTERNAL CONTROLS. WE EXPRESS AN OPINION
16 ON INTERNAL CONTROLS. HOWEVER, IF DURING OUR AUDIT
17 WE BECOME AWARE OF A DEFICIENCY IN INTERNAL CONTROLS
18 THAT RISES TO THE LEVEL THAT WE CALL A SIGNIFICANT
19 DEFICIENCY OR MATERIAL, WE'D BE REQUIRED TO REPORT
20 THOSE TO THOSE CHARGED WITH GOVERNANCE. AND WE'RE
21 HAPPY TO REPORT THAT NO SUCH DEFICIENCIES WERE
22 REPORTED FOR THE YEAR ENDED JUNE 30, 2015.

23 AND AS ALSO A PART OF THAT REPORT WE NOTED
24 NO NONCOMPLIANCE OF LAWS OR REGULATIONS, CONTRACTS,
25 OR GRANTS THAT WOULD CAUSE A MATERIAL MISSTATEMENT

BARRISTERS' REPORTING SERVICE

1 OF THE FINANCIAL STATEMENTS.

2 AND WITH THAT SAID, I'LL OPEN IT UP TO ANY
3 QUESTIONS FOR US.

4 CHAIRPERSON YEE: QUESTIONS, MEMBERS?
5 OKAY. HEARING NONE, I BELIEVE WE WILL TAKE THAT
6 INTO CONSIDERATION. THANK YOU SO MUCH.

7 MR. CONNER: ALL RIGHT. THANK YOU.

8 CHAIRPERSON YEE: GOOD. NEXT WE WILL
9 HAVE A PRESENTATION BY OUR STATE CONTROLLER AUDIT.
10 JAMES SPANO. KIND OF THE ROLE OF THE CONTROLLER'S
11 OFFICE IS TO CONDUCT A QUALITY REVIEW OF THE MGO
12 AUDIT THAT WE JUST HEARD.

13 MR. SPANO: GOOD MORNING, COMMITTEE
14 MEMBERS. THANK YOU FOR ALLOWING THE STATE
15 CONTROLLER TO PRESENT OUR REVIEW RESULTS. MY NAME
16 IS JIM SPANO. I'M AN AUDIT BUREAU CHIEF FOR THE
17 STATE CONTROLLER'S OFFICE, DIVISION OF AUDITS.
18 UNDER THE AUTHORITY OF HEALTH AND SAFETY CODE
19 SECTION 125290.3, THE STATE CONTROLLER'S OFFICE
20 CONDUCTED A QUALITY CONTROL REVIEW OF MACIAS, GINI &
21 O'CONNELL'S WORKPAPERS RELATED TO ITS AUDIT OF CIRM
22 FOR THE FISCAL YEAR ENDED JUNE 30, 2015.

23 WE DETERMINED THAT THE AUDIT WAS PERFORMED
24 IN ACCORDANCE WITH APPLICABLE AUDITING STANDARDS AND
25 CALIFORNIA BUSINESS AND PROFESSIONS CODE. AS SUCH,

BARRISTERS' REPORTING SERVICE

1 WE ISSUED A REPORT ON JANUARY 26, 2016.

2 I'M AVAILABLE FOR ANY QUESTIONS.

3 CHAIRPERSON YEE: MEMBERS, QUESTIONS?

4 THANK YOU, JIM.

5 MR. SPANO: THANK YOU.

6 CHAIRPERSON YEE: WHY DON'T WE MOVE ON,

7 THEN, TO ITEM NO. 6. THIS IS RELATED TO CIRM'S

8 STRATEGIC AND OPERATIONAL REVIEW. AND LET ME

9 WELCOME RANDY MILLS. GOOD MORNING, DR. MILLS.

10 DR. MILLS: THANK YOU VERY MUCH FOR HAVING

11 ME TODAY. IT'S MY PLEASURE TO COME OUT AND SPEAK

12 WITH THE COMMITTEE. I BROUGHT BACKUP. THAT IS MY

13 SON, CHASE MILLS. ANY HARD QUESTIONS, I WILL REFER

14 TO HIM.

15 CHAIRPERSON YEE: WELCOME, CHASE.

16 DR. MILLS: I'M VERY EXCITED TO BE HERE

17 TODAY AND TALK TO YOU ABOUT WHAT I THINK IS THE

18 TREMENDOUS WORK THAT'S BEING DONE BY THE TEAM AT

19 CIRM. IN FACT, IN PREPARING FOR TODAY, I THINK IT

20 SIGNIFICANTLY INCREASED MY EXCITEMENT AND ENTHUSIASM

21 ABOUT THE AGENCY AS WELL AS THE REST OF THE

22 LEADERSHIP TEAM. AND I'M VERY PLEASED TO BE ABLE TO

23 REPORT TO YOU TODAY, NOT JUST ASPIRATIONALLY WHAT WE

24 MIGHT BE DOING, BUT ACTUALLY TANGIBLE, REAL RESULTS

25 AND PROGRESS THAT THE AGENCY IS MAKING. SO LET'S

BARRISTERS' REPORTING SERVICE

1 GET INTO IT.

2 SO WE'LL TRY IT THIS WAY. SO THE FIRST
3 THING I DO ANY TIME I GIVE A PRESENTATION LITERALLY
4 ANYWHERE, INCLUDING TO OUR BOARD OR ANYWHERE ELSE,
5 IS START BY REVIEWING OUR MISSION. WE HAVE A SIMPLE
6 MISSION, TEN WORDS: ACCELERATE STEM CELL TREATMENTS
7 TO PATIENTS WITH UNMET MEDICAL NEEDS. THIS IS OUR
8 MOVABLE ORIENTING POINT. THIS IS OUR TRUE NORTH.
9 WE NEVER DEVIATE FROM THIS AT CIRM. AND THAT ENDS
10 UP BEING VERY HELPFUL IN CREATING ALIGNMENT FROM OUR
11 BOARD THROUGH OUR LEADERSHIP TEAM THROUGH THE
12 REMAINDER OF THE TEAM AT CIRM AND OUR STAKEHOLDERS
13 THAT WE WORK WITH.

14 TO GIVE YOU A LITTLE BIT OF AN IDEA OF
15 WHAT CIRM DOES, WE ACTUALLY HAVE A PRETTY BROAD
16 PORTFOLIO. WE HAVE FIVE MAJOR ACTIVITIES THAT WE
17 GET INVOLVED IN. THE LAST IS INFRASTRUCTURE. WE
18 LITERALLY BUILD THINGS. WE HAVE 12 MAJOR RESEARCH
19 FACILITIES, WE HAVE THREE WHAT WE CALL ALPHA CLINICS
20 WHERE WE ACTUALLY TREAT PEOPLE WITH STEM CELL
21 THERAPIES THAT ARE UNDERGOING CLINICAL TRIALS, WE
22 HAVE AN IPS OR STEM CELL BANK THAT WE HAVE, WE HAVE
23 A GENOMICS CENTER. WE JUST OPENED UP TWO VERY
24 INTERESTING PIECES CALLED THE ACCELERATING AND THE
25 TRANSLATING CENTER. SO THAT'S OUR INFRASTRUCTURE

BARRISTERS' REPORTING SERVICE

1 PROGRAMS.

2 ON THE OTHER SIDE IS EDUCATION. AND THE
3 EDUCATIONAL SIDE, WE ACTUALLY TRAIN EVERYTHING FROM
4 HIGH SCHOOL STUDENTS THROUGH POSTDOCTORATE STUDENTS
5 IN TECHNIQUES, HOW TO WORK WITH STEM CELLS, HOW TO
6 USE THEM SO THEY CAN GO OUT AND ENTER THE WORKFORCE
7 IN A PRODUCTIVE MANNER. AND THEN IN BETWEEN WE HAVE
8 REALLY WHAT'S THE CORE OF CIRM, WHICH IS OUR
9 DISCOVERY, TRANSLATIONAL, AND CLINICAL PROGRAMS. SO
10 THIS IS WHERE WE TAKE GREAT IDEAS FOR STEM CELL
11 TREATMENTS AND WE MOVE THEM ALONG FROM THE EARLIEST
12 STAGES OF THE DEVELOPMENT ALL THE WAY THROUGH WHAT
13 WE CALL REGISTRATION OF CLINICAL TRIALS.

14 SO WHAT WE REALLY WANT TO DO IS FIND A WAY
15 TO MAKE THIS WORK IN THE MOST EFFECTIVE MANNER
16 POSSIBLE. AND SO LAST YEAR WE EMBARKED ON CREATING
17 A NEW STRATEGIC PLAN. I'M AT THAT TIME RELATIVELY
18 NEW TO THE AGENCY. I'VE BEEN HERE JUST A LITTLE
19 OVER TWO YEARS NOW. AFTER ABOUT A YEAR OF BEING
20 WITH THE AGENCY, I THOUGHT IT WOULD BE A GOOD THING
21 TO DO. NOW, STRATEGIC PLANS CAN BE BORING. THEY
22 CAN BE TEDIOUS. THEY CAN INVOLVE LOTS OF OUTSIDE
23 CONSULTANTS AND GANTT CHARTS AND ALL KIND OF THINGS
24 LIKE THAT. I'VE DONE IT A NUMBER OF TIMES, AND I
25 FIND IT'S BEST IF YOU JUST KEEP IT SIMPLE.

BARRISTERS' REPORTING SERVICE

1 THERE'S REALLY THREE QUESTIONS THAT WE'RE
2 TRYING TO ASK. ONE IS WHERE ARE WE NOW. AND THIS
3 IS USUALLY THE HARDEST ONE TO ANSWER BECAUSE IT
4 REQUIRES YOU TO BE BRUTALLY HONEST. WHERE REALLY
5 ARE WE NOW?

6 THE SECOND THING IS WHERE DO YOU WANT TO
7 GO. AND THEN, LASTLY, HOW YOU GOING TO GET THERE?
8 HOW ARE YOU GOING TO CONNECT THOSE TWO DOTS? AND IF
9 YOU'RE SUCCESSFUL WITH THIS, YOU'LL CREATE SOMETHING
10 THAT WILL HAVE A LOT OF VALUE. AND THAT VALUE IS,
11 ONE, SITUATIONAL AWARENESS. SO EVERYONE WILL IN A
12 TRANSPARENT MANNER BE ABLE TO SEE WHAT THE AGENCY
13 AND THE ORGANIZATION IS DOING. WE'LL HAVE VERY
14 MEASURABLE GOALS. SO WE'RE GOING TO KNOW WHERE
15 WE'RE GOING TO GO, AND WE'RE GOING TO KNOW IF WE'RE
16 GOING TO GET THERE OR NOT, AND WE'RE GOING TO HAVE
17 ORGANIZATIONAL CLARITY. EVERYONE IS GOING TO KNOW
18 THEIR ROLES IN HOW WE GOT THERE.

19 AND SO THAT WAS THE PURPOSE OF THE
20 STRATEGIC PLANNING PROCESS; AND I THINK, I HOPE AS
21 YOU WILL SEE, IT'S BEEN QUITE SUCCESSFUL FORM.

22 SO STARTING WITH UNDERSTANDING WHERE WE
23 ARE, WE WENT OUT, WE CALL IT THE CIRM ROADSHOW, WE
24 WENT OUT AND WE TALKED TO JUST ABOUT EVERYONE WE
25 COULD GET AHOLD OF, ALL OF OUR MAJOR RESEARCH

BARRISTERS' REPORTING SERVICE

1 FACILITIES, WE LITERALLY WENT AND DID PRESENTATIONS.
2 WE WOULD TALK TO THEM, AND THEN WE COULD SIT AND
3 LISTEN, AND LISTENED A LOT. WE MET WITH INDUSTRY,
4 WE MET WITH PATIENTS, WE MET WITH PATIENT ADVOCACY
5 GROUPS. AND THIS IS SOMETHING, BY THE WAY, THAT
6 WE'VE ACTUALLY JUST CONTINUED. SO THE CIRM ROADSHOW
7 CONCEPT, EVEN THOUGH WE LAUNCHED THE STRATEGIC PLAN,
8 WE'VE ACTUALLY NOW GONE AND LAUNCHED ANOTHER CIRM
9 ROADSHOW BECAUSE YOU JUST CAN'T LISTEN TO THE PEOPLE
10 YOU'RE WORKING WITH ENOUGH.

11 AND SO OUT OF THIS LISTENING PROCESS, WE
12 LEARNED SOME STUFF. ONE IS THAT CIRM EXISTED, THIS
13 IS IN SORT OF THE 2014 WORLD, AS AN INITIATIVE-BASED
14 AGENCY VERSUS THE SYSTEMS-BASED AGENCY. THIS IS THE
15 PROBABLY THE SINGLE BIGGEST CHANGE THAT WE'VE MADE.
16 BUT WHAT I MEAN BY AN INITIATIVE-BASED AGENCY, I
17 MEAN EVERYTHING WE DID WAS KIND OF A ONE-OFF. THERE
18 WASN'T A PROCESS, THERE WASN'T A PREDICTABLE,
19 REPEATABLE PROCESS TO WHAT WE DID. AND THAT IS NOT
20 A CRITICISM. THAT'S ACTUALLY FOR WHEN CIRM WAS
21 STARTED, THAT WAS HOW IT NEEDED TO BE BECAUSE THERE
22 WASN'T ENOUGH SUSTAINABLE DEMAND FOR OUR PROGRAMS.
23 AND SO INSTEAD, WHAT THEY DO IS THEY WAIT. IF THEY
24 WANTED TO DO A BASIC BIOLOGY AWARD, THEY WAIT UNTIL
25 THERE WAS SUFFICIENT NUMBERS OF PEOPLE THAT COULD

BARRISTERS' REPORTING SERVICE

1 APPLY FOR THAT; AND THEN WHEN THEY FINALLY HAD
2 ENOUGH DEMAND, THEY WOULD MAKE THAT AWARD. THE
3 WORLD'S CHANGED THOUGH, AND THE WORLD'S CHANGED SO
4 THERE'S SUFFICIENT DEMAND FOR ALL THESE THINGS TO BE
5 RUNNING CONTINUOUSLY, SO WE'RE ABLE TO MAKE THAT
6 CHANGE.

7 FORTUNATELY, MOST OF THE PRIORITIES AMONG
8 STAKEHOLDERS WERE ALIGNED, AND THAT ALIGNMENT WAS
9 COMPLETE WITH THE BOARD. A HUNDRED PERCENT
10 UNANIMOUS CENTERING AROUND OUR MISSION AND WHAT IT
11 IS WE SHOULD AND SHOULDN'T BE DOING.

12 THE ONE THING THAT JUMPED OFF THE PAGE WAS
13 THE OPPORTUNITY THAT EXISTS FOR TRANSLATIONAL
14 RESEARCH. AND TRANSLATIONAL RESEARCH IS AFTER
15 YOU'VE COME UP WITH AN IDEA AND YOU'VE DONE ENOUGH
16 WORK TILL YOU'VE IDENTIFIED A SINGLE STEM CELL,
17 LET'S SAY, THAT YOU WANT TO TAKE. FROM THAT TIME TO
18 THE TIME IT TAKES TO GET INTO CLINICAL TRIALS, FOR
19 STEM CELLS THAT'S EIGHT YEARS. FOR ANYTHING THAT'S
20 NOT A STEM CELL, THAT SAME JOURNEY TAKES 3.2 YEARS.
21 SO THERE WAS A REAL OPPORTUNITY FOR US TO ACCELERATE
22 THAT.

23 INDUSTRY, STILL NOT SO FAVORABLE ON THE
24 STEM CELLS, AND I'LL SHOW MORE ABOUT THAT IN A
25 SECOND. AND THEN THE REGULATORY ENVIRONMENT IS JUST

BARRISTERS' REPORTING SERVICE

1 NOT DRIVING THE RESULTS THAT WE WANT TO SEE.

2 SECOND THING ABOUT WHERE WE ARE WAS REALLY
3 GETTING CLARITY AROUND OUR FINANCIAL SITUATION. I
4 KNOW WE HAVE FINANCIAL AUDITS, AND CHILA IS GOING TO
5 TALK ABOUT THE BUDGET; BUT ON A BIG PICTURE, LET'S
6 STAND BACK AND LET'S LOOK AT THIS IN AS SIMPLE AND
7 CLEAR A TERMS AS WE POSSIBLY CAN. AND THIS IS HOW I
8 DO IT, SO I'LL SHOW IT TO YOU BECAUSE IT HELPS ME IN
9 MY MIND.

10 BUT BASICALLY WE HAVE, I CALL THIS MEET
11 THE BUCKETS. WE HAVE TWO BUCKETS. WE HAVE AWARD
12 BUCKETS, WHICH IS THE MONEY THAT WE USE TO DISBURSE
13 TO MAKE AWARDS. AND WE HAVE OUR ADMINISTRATIVE
14 BUCKET, JUST A LITTLE BUCKET. THAT'S THE MONEY WE
15 USE TO RUN AND OPERATE CIRM. WHEN EITHER ONE OF
16 THOSE BUCKETS GOES TO ZERO, CIRM IS OVER. THE
17 ADMINISTRATIVE BUCKET IS ABOUT 180 MILLION. THAT'S
18 REALLY A ONE-WAY STREET. THAT MONEY LEAVES AND IT
19 JUST, UNLESS SOMETHING MIRACULOUS HAPPENS, IT
20 DOESN'T COME BACK. BUT THE AWARD BUCKET ISN'T THAT
21 WAY. AND THIS HAS BEEN A SOURCE OF A LOT OF
22 CONFUSION AT CIRM. SO WHEN I GOT TO CIRM, IT WAS
23 ALMOST LIKE IT WAS A TAGLINE FOR THE AGENCY. CIRM,
24 THE AGENCY THAT'S GOING TO RUN OUT OF MONEY IN 2016
25 OR 17. AND IT'S BECAUSE WE DIDN'T FULLY UNDERSTAND

BARRISTERS' REPORTING SERVICE

1 THAT THIS BUCKET IS ACTUALLY A TWO-WAY STREET.

2 WHEN WE MAKE AWARDS, THIS IS LAST YEAR,
3 FOR EXAMPLE, WE MADE \$155 MILLION IN NEW AWARDS LAST
4 YEAR. AND THAT'S GOOD. BUT WE REALLY ARE A
5 MILESTONE-BASED AGENCY. I'LL BE TALKING A LOT MORE
6 ABOUT THAT. AND WHAT THAT MEANS IS IF A PROJECT
7 FAILS OR SOMETHING HAPPENS, IT GOES AWRY, IT JUST
8 DOESN'T WORK, WHATEVER MONEY HASN'T BEEN SPENT COMES
9 BACK INTO THE UNCOMMITTED BUCKET. SO WE MOVE
10 COMMITTED BETWEEN UNCOMMITTED. SO RIGHT NOW WE HAVE
11 ABOUT -- JUST ABOUT \$650 MILLION THAT'S UNCOMMITTED.
12 BUT BECAUSE OF THAT RETURN RATE, WE'LL ACTUALLY BE
13 ABLE TO MAKE ABOUT 800 MILLION IN NEW AWARDS BECAUSE
14 THERE WILL BE RECYCLING.

15 SO WHEN WE LOOK AT THAT, \$800 MILLION
16 MAKES CIRM VERY, VERY RELEVANT AND HAS AN ENORMOUS
17 POTENTIAL FOR IMPACT. WE MIGHT BE IN THE SECOND
18 HALF OF OUR LIFE, BUT WE'RE NOT IN A TWO-MINUTE
19 DRILL. WE HAVE THE ABILITY TO STILL HAVE A
20 TREMENDOUS IMPACT AND WILL HAVE A TREMENDOUS IMPACT
21 IN THE FIELD OF STEM CELL THERAPY AND REGENERATIVE
22 MEDICINE.

23 AND SO WE TOOK ALL THAT, AND I'M A PILOT
24 SO I LIKE TO USE AIRPLANE ANALOGIES, WE CREATED THIS
25 ANALOGY. WHAT WE'RE REALLY TRYING TO DO IS CREATE A

BARRISTERS' REPORTING SERVICE

1 SYSTEM NOW, A SYSTEM THAT ACCELERATES GREAT IDEAS IN
2 STEM CELL THERAPIES TO CURES. AND THE POINT OF CIRM
3 IS THAT CIRM SHOULD BE ABLE TO DO THIS PREDICTABLY
4 AT A HIGHER VOLUME, A HIGHER SPEED, AND WITH GREATER
5 QUALITY THAN IF CIRM DIDN'T EXIST. NOW,
6 BENCHMARKING THIS IS DIFFICULT. IT'S DIFFICULT FOR
7 US TO ACTUALLY BE ABLE TO PROVE THAT DIRECTLY. THIS
8 ISN'T A CONTROLLED TEST. WE DON'T HAVE SOME
9 PROGRAMS THAT WE USE IN CIRM AND SOME PROGRAMS THAT
10 WE DO AND DON'T. BUT THERE ARE WAYS THAT WE CAN
11 MEASURE, AND WE HAVE BECOME A METRICS-FOCUSED
12 ORGANIZATION FOR SURE. AND I THINK I'LL BE ABLE TO
13 MAKE A PRETTY GOOD CASE THAT THIS IS ACTUALLY
14 STARTING TO WORK.

15 THE OTHER POINT I WANT TO MAKE ABOUT THIS
16 SLIDE IS WE'RE NOT TRYING TO BE LUCKY. WE'RE NOT
17 TRYING TO HAVE THE ONE-OFF SUCCESS. I DON'T WANT TO
18 BE GREAT AT WINNING THE LOTTERY. I WANT SOMETHING
19 THAT'S REPRODUCIBLE, NOT JUST THAT ONE CURE GETS
20 THROUGH, BUT THAT A PIPELINE OF CURES CONSISTENTLY
21 GETS THROUGH. AND WHEREVER YOU ARE IN THAT
22 PIPELINE, THINGS ARE MOVING FASTER AND BETTER THAN
23 IF CIRM DIDN'T EXIST. THAT WAS WHAT WE SET OUT TO
24 DO. AND WE HAD A STRATEGIC PLAN THAT WE BUILT
25 AROUND THAT. AND THERE'S THREE THEMES TO OUR

BARRISTERS' REPORTING SERVICE

1 STRATEGIC PLAN: PUSH, PULL, AND LEVEL.

2 SO HISTORICALLY CIRM EXISTS AS A PUSHING
3 AGENCY. IN THIS METAPHOR YOU CAN IMAGINE IF WHAT
4 CIRM'S MISSION IS TRYING TO PUSH IS THIS GIANT
5 BOULDER OF STEM CELLS OVER THIS HILL TO THE VALLEY
6 OF CURES BELOW, WE'VE BEEN IN THE PUSHING BUSINESS
7 ON THAT. AND AS I SAID PREVIOUSLY, THAT PUSHING
8 BUSINESS WAS LARGELY ON A ONE-OFF SORT OF
9 INITIATIVE. WE DIDN'T HAVE A MACHINE THAT WAS
10 PUSHING. WE JUST HAD INDIVIDUAL INITIATIVES THAT
11 PUSHED ON THIS BOULDER. AND SO WE MADE FOUR KEY
12 CHANGES ON THE PUSHING SIDE OF WHAT WE DID. AND
13 I'LL SHOW THOSE RESULTS.

14 THE FIRST IS WE STANDARDIZED RECURRING
15 PROGRAM OFFERINGS. SO JUST TO GIVE YOU AN EXAMPLE
16 IN THE PAST, EVERY ONCE IN A WHILE, MAYBE EVERY 18
17 MONTHS, WE'D SAY, HEY, IT WOULD BE GREAT IF WE HAD
18 SOME CLINICAL TRIALS. LET'S ISSUE AN RFA TO SEE IF
19 ANYBODY HAS ANY CLINICAL TRIALS THEY WANT TO RUN.
20 WE CHANGED THAT NOW TO IT'S ALWAYS OPEN. WE ALWAYS
21 WANT CLINICAL TRIALS. YOU CAN ALWAYS APPLY. AND SO
22 IT RECURS OVER AND OVER AGAIN.

23 THE SECOND THING IS -- SO NOW THERE'S A
24 SCHEDULE AND WE KNOW WHEN THESE PROGRAMS ARE THERE
25 AND YOU CAN APPLY. THE SECOND THING WE DID, WE

BARRISTERS' REPORTING SERVICE

1 INCREASED THE SPEED OF THIS. SO ON ONE HAND IT'S
2 GREAT TO HAVE A PROCESS THAT'S FREQUENT, BUT IT
3 TAKES FOREVER. AND THAT'S NOT GOOD HERE. SO WE
4 NEED TO GET FASTER.

5 THE THIRD THING IS WE IMPLEMENTED
6 SIGNIFICANT MILESTONE-BASED DISBURSEMENTS. I'M
7 GOING TO TALK MORE ABOUT MILESTONE-BASED
8 DISBURSEMENTS. I DON'T KNOW THAT THERE'S A SINGLE
9 THING WE'VE DONE THAT'S HAD A BIGGER IMPACT THAN
10 THIS STUFF.

11 AND THEN, LASTLY, WE ESTABLISHED VERY
12 CLEAR AND MEASURABLE GOALS FOR THE TEAM.

13 SO FREQUENT AND STANDARDIZED OFFERINGS.
14 SO, AS I SAID, THE DISCOVERY, TRANSLATIONAL, AND
15 CLINICAL PORTFOLIO, THAT'S THE CORE OF CIRM'S
16 ENGINE. THESE THINGS USED TO BE CALLED GRANT
17 WHACK-A-MOLE. AN RFA WOULD POP UP, IT WOULD BE OPEN
18 FOR A LITTLE WHILE AND WOULD GO AWAY. IF YOU WERE A
19 RESEARCHER, YOU HAD NO IDEA WHEN OR IF EVER THAT RFA
20 WOULD OPEN BACK UP AGAIN. AND THAT CREATED A LOT OF
21 BEHAVIOR THAT WE DIDN'T LIKE. WE WOULD HAVE PEOPLE
22 APPLYING FOR GRANTS EARLY. WE WOULD HAVE THEM
23 APPLYING FOR THE WRONG GRANTS. AND SO WE SAID,
24 LOOK, NOW THAT WE UNDERSTAND OUR FINANCIAL
25 SITUATION, WE KNOW THAT WE'RE GOING TO BE IN

BARRISTERS' REPORTING SERVICE

1 BUSINESS THROUGH 2020. SO LET'S JUST HAVE A
2 STANDARDIZED PROGRAM OFFER. DISCOVERY, WE'RE GOING
3 TO OFFER THAT PROGRAM TWICE A YEAR. TRANSLATIONAL,
4 WE'RE GOING TO OFFER THAT PROGRAM THREE TIMES A
5 YEAR. AND CLINICAL, WE'RE GOING TO OFFER THAT
6 PROGRAM 12 TIMES A YEAR. ESSENTIALLY IT'S ALWAYS
7 OPEN.

8 AND THAT HAS HAD SIGNIFICANT EFFECTS
9 ON -- AGAIN, WHAT WE'RE TRYING TO DO IS INCREASE
10 VOLUME, SPEED, AND QUALITY. THESE METRICS, I THINK,
11 ARE FANTASTIC. SO THE NUMBER OF REVIEW CYCLES WE
12 OFFER A YEAR HAS INCREASED FOURFOLD, BUT AT THE SAME
13 TIME THE COST PER APPLICATION HAS DECREASED 57
14 PERCENT. SO WE'RE GETTING THINGS STANDARDIZED,
15 WE'RE LEARNING HOW TO DEAL WITH THEM QUICKER, WE'RE
16 GETTING SMARTER, WE'RE USING THINGS LIKE
17 TELECONFERENCES AND THINGS LIKE THAT. THE NUMBER OF
18 AWARDS WE'RE MAKING HAS GONE UP 33 PERCENT, YET THE
19 TIME TO APPROVE THOSE AWARDS HAS FALLEN BY 82
20 PERCENT. IT'S ONE OF THE MOST DRAMATIC FIGURES.
21 FOR A CLINICAL TRIAL HISTORICALLY IT USED TO TAKE US
22 ABOUT 22 MONTHS. IF YOU HAD A CLINICAL TRIAL AND
23 YOU WERE READY TO GO, IT WOULD TAKE US ABOUT 22
24 MONTHS TO AWARD YOU THAT GRANT FOR A CLINICAL TRIAL.
25 WE CAN NOW MAKE THE ADJUDICATION ON THAT, HAVE IT

BARRISTERS' REPORTING SERVICE

1 REVIEWED IN UNDER 60 DAYS, AND IT'S ABOUT 85 DAYS
2 FROM THE TIME YOU APPLY FOR THE BOARD TO APPROVE IT.
3 INCREDIBLE REDUCTION THERE.

4 AND THEN FROM A QUALITY STANDPOINT, THE
5 NUMBER OF APPLICATIONS THAT ARE ACTUALLY IMPROVED
6 BEFORE THEY'RE APPROVED HAS GONE UP 70, 75 PERCENT.
7 AND I THINK PROBABLY ONE OF THE -- THERE ARE SO MANY
8 OTHER STRIKING EXAMPLES, AND IT'S DRIVING CHILA
9 ABSOLUTELY CRAZY AS SHE'S TRYING TO BUDGET FOR THIS
10 BECAUSE OUR PRODUCTIVITY AND OUR EFFICIENCY ARE
11 GOING THROUGH THE ROOF. AND SO WE'RE MAKING HER JOB
12 A BIT OF A MOVING TARGET. SO OUR APPLICATIONS ARE
13 UP 33 -- OR OUR NUMBER OF AWARDS ARE UP 33 PERCENT,
14 OUR NUMBER OF REVIEW CYCLES ARE UP FOURFOLD. OUR
15 LEGAL COSTS ARE DOWN 32 PERCENT. AND THE REASON OUR
16 LEGAL COSTS ARE DOWN 32 PERCENT IS BECAUSE WE'VE
17 STANDARDIZED THINGS. WE HAVE TEMPLATE CONTRACTS.
18 YOU APPLY FOR AN AWARD, THIS IS WHAT YOU ARE GOING
19 TO SEE. LIKE IT OR DON'T LIKE IT, BUT WE'RE NOT
20 GOING TO DO ALL THESE ONE-OFF NEGOTIATIONS EVERY
21 TIME. SO WE'RE SEEING TREMENDOUS AMOUNT OF
22 EFFICIENCY AND PRODUCTIVITY COMING FROM THIS SYSTEM.

23 THE SECOND THING THAT I TALKED ABOUT WAS
24 THIS GOING TO A MILESTONE-BASED DISBURSEMENT SYSTEM.
25 AND THE CHANGE HERE IS IT'S THE DISBURSEMENTS ARE

BARRISTERS' REPORTING SERVICE

1 MILESTONE BASED. SO WE USED TO HAVE MILESTONES, BUT
2 OUR DISBURSEMENTS WERE TIME BASED. AND SO THE WAY
3 IT WOULD WORK IS YOU WOULD HAVE A GRANT AND WE WOULD
4 PAY YOU EVERY SIX MONTHS OR EVERY QUARTER, AND YOU
5 HAD MILESTONES, GO/NO-GO MILESTONES. AND IF YOU
6 DIDN'T HIT ONE OF THOSE MILESTONES, EVENTUALLY IT
7 WOULD GET BACK TO CIRM AND EVENTUALLY WE WOULD THINK
8 ABOUT WHAT TO DO.

9 BUT THE WAY THIS SYSTEM -- THE DEFAULT
10 MODE FOR THE SYSTEM WAS TO KEEP DISBURSING MONEY.
11 AND WE CHANGED THAT. WE FLIPPED THAT COMPLETELY
12 AROUND. AND NOW WHEN WE HAVE AN AWARD, WE TAKE THAT
13 AWARD AND WE DIVIDE IT UP INTO MILESTONES. IF THIS
14 WAS A \$3 MILLION CLINICAL TRIAL, IT MIGHT BE FIRST
15 PATIENT, 30TH PATIENT, 66, AND A HUNDRED PERCENT.
16 WE'LL DIVIDE IT UP INTO MILESTONES. AND WE GIVE YOU
17 ENOUGH MONEY RIGHT OUT OF THE GATE TO COMPLETE YOUR
18 FIRST OPERATIONAL MILESTONE. BUT WE DON'T GIVE YOU
19 ANY MORE MONEY UNTIL YOU COMPLETE THAT OPERATIONAL
20 MILESTONE. IT IS INCUMBENT UPON YOU TO SEND THE
21 OBJECTIVE DATA TO US THAT YOU'VE HIT IT. AND SO IN
22 THAT WAY WE DON'T PAY UNLESS THE OPERATIONAL
23 MILESTONE IS HIT INSTEAD OF THE WAY IT USED TO BE,
24 WHEREAS, WE WOULD HAVE TO STOP PAYMENT. WE WOULD
25 HAVE TO TAKE ACTION. TO STOP HERE, THEY HAVE TO

BARRISTERS' REPORTING SERVICE

1 TAKE ACTION TO GET PAID. IF THEY GO LONG, IF IT
2 TAKES THEM TOO LONG, THEY HAVE TO MAKE UP THAT GAP.
3 WE ACTUALLY PUT IT AS PART OF THE APPLICATION
4 PROCESS TO WHERE CONTINGENCY FUNDING IS A REQUIRED
5 COMPONENT. THEY HAVE TO TELL US, IF THERE'S A
6 PROBLEM, HOW THEY'RE GOING TO MAKE UP THAT MONEY AND
7 WE'RE NOT THAT ANSWER.

8 INTERESTINGLY, IF THEY CAN DO IT QUICKER
9 AND THEY CAN REALIZE SAVINGS, WE LET THEM BANK THAT
10 MONEY AND CARRY IT FORWARD ALL THE WAY THROUGH THE
11 END OF THE AWARD. AND IF AT THE END OF THE AWARD,
12 THEN WE'LL APPROVE CERTAIN ACTIVITIES THAT THEY CAN
13 DO. IT USED TO BE WHERE THEY WERE ACTUALLY
14 FINANCIALLY DISINCENTIVIZED TO MOVE FASTER BECAUSE
15 IF THEY MOVE FASTER, THEIR AWARD WOULD SHRINK
16 BECAUSE THEY WOULDN'T BE GETTING THEIR OWN GRANTS.
17 WE WANTED TO LINE UP WHAT WE WANTED, WHICH WAS
18 PERFORMANCE AND SPEED.

19 HOW DOES THIS WORK? IT'S DRAMATIC. THE
20 NUMBER OF -- I DON'T KNOW THAT WE HAVE A BETTER
21 METRIC, A SURROGATE METRIC, THAN THE NUMBER OF
22 MILESTONES HIT ON TIME. THE NUMBER OF MILESTONES
23 HIT ON TIME HAS JUMPED FROM 19 PERCENT UNDER THE 1.0
24 SYSTEM TO 77 PERCENT UNDER THIS SYSTEM. IT IS AN
25 INCREDIBLE MOTIVATING FACTOR.

BARRISTERS' REPORTING SERVICE

1 ANOTHER WAY TO LOOK AT THAT IS ON PATIENT
2 ENROLLMENT. EVERYONE UNDERSTANDS PATIENTS AND
3 PATIENT ENROLLMENTS. WE DON'T GET ANYWHERE UNLESS
4 WE PUT PATIENTS INTO CLINICAL TRIALS, GET THEM
5 TREATED, AND GET THEM GOING. THESE ARE OUR
6 ENROLLMENT FIGURES PER QUARTER. IT'S A BEAUTIFUL
7 GRAPH. I LOVE THAT GRAPH. BECAUSE THIS IS VERY
8 CLEAR, REAL OBJECTIVE AND TANGIBLE PROGRESS.

9 IF YOU ACTUALLY LOOK AT THIS, THERE'S
10 ACTUALLY TWO SLOPES HERE. SO THE GRAPH ITSELF IS A
11 CUMULATIVE NUMBER OF PATIENTS. IF YOU LOOK AT THE
12 SLOPE OF THAT CURVE, THAT GIVES YOU, THEN, THE RATE,
13 HOW FAST WE'RE PUTTING PATIENTS INTO THESE CLINICAL
14 TRIALS. AND THERE'S ACTUALLY TWO DISTINCT CURVES.
15 THIS IS THE CURVE THAT'S CREATED PRIMARILY BY
16 CLINICAL TRIALS THAT WE HAVE UP AND RUNNING UNDER
17 THE 1.0 SYSTEM, WHICH DIDN'T HAVE THAT MILESTONE
18 BASE. THIS IS THE SLOPE OF THE CURVE WHEN WE
19 TRANSFERRED FROM 1.0 TO 2.0. AND, YES, WE ACTUALLY
20 TRANSFERRED. SO IF WE HAD AWARDS THAT WERE UNDER
21 THE 1.0 SYSTEM AND WE COULD, JAMES AND HIS GROUP
22 WOULD GO OUT AND DO EVERYTHING THEY COULD TO PUT
23 THEM ON A 2.0 SYSTEM. HOW BIG OF A DIFFERENCE IS
24 THESE SLOPES? IN THAT GRAPH YOU MAYBE CAN'T TELL.
25 IT'S THIS BIG.

BARRISTERS' REPORTING SERVICE

1 WE ENROLLED ON AVERAGE 1.66 PATIENTS PER
2 TRIAL ON THE 1.0 SYSTEM. WE CAN DO THAT AT 4.49,
3 ALMOST FOUR AND A HALF PATIENTS PER TRIAL. THE
4 DIFFERENCE IS THAT WOULD BE A TRIAL THAT UNDER THE
5 1.0 SYSTEM WOULD TAKE TWO AND A HALF YEARS NOW TAKES
6 LESS THAN A YEAR, 11 MONTHS TO DO. IT'S CLEARLY
7 WORKED.

8 SO WE'VE TAKEN THAT INITIATIVE BASE,
9 PUSHING THAT BOULDER OVER THE HILL, AND WE'VE
10 REPLACED WITH A MACHINE THAT IS OPERATIONALLY
11 EXCELLENT AT PUSHING.

12 WHAT WE NOTICED HERE, THAT WE'RE DOING A
13 LOT OF PUSHING, BUT THERE'S NOT ANYONE ON THE OTHER
14 SIDE OF THIS HILL DOING ANY PULLING. AND THAT'S A
15 PROBLEM. AND WE LOOKED AT OUR NUMBERS. OUR NUMBERS
16 CONFIRMED THAT WAS A PROBLEM. SO IN OUR HISTORY, 91
17 PERCENT OF OUR AWARDS HAVE GONE TO ACADEMIC
18 INSTITUTIONS AND ONLY 9 PERCENT TO INDUSTRY. THE
19 REASON THAT'S A PROBLEM IS THAT, IN ORDER FOR US TO
20 COMPLETE OUR MISSION, GET IT ALL THE WAY DONE, HELP
21 THESE ACTUAL PATIENTS WITH UNMET MEDICAL NEEDS, WE
22 KNOW WE NEED INDUSTRY ON THE BACK SIDE OF THAT TO
23 COMPLETE THAT. ACADEMIC CENTERS ARE GREAT AT COMING
24 UP WITH THE NEW IDEAS AND TO IMPROVE THE CONCEPT
25 TESTING, AND WORKING OUT MECHANISMS AND THE LIKE,

BARRISTERS' REPORTING SERVICE

1 BUT WE NEED INDUSTRY TO TAKE BASICALLY THE BALL TO
2 THE GOAL LINE AND MAKE IT SO WE CAN ACTUALLY TREAT
3 POPULATIONS OF PEOPLE. AND SO WE WANTED TO FIX
4 THAT.

5 THERE'S TWO THINGS WE DID OR I SHOULD SAY
6 ARE DOING THE FIXES. THE FIRST WAS JUST BE EASIER
7 TO DO BUSINESS WITH. THAT SOUNDS KIND OF COMMON
8 SENSE, BUT I'LL GIVE YOU JUST A VERY REAL EXAMPLE.
9 LET'S GO BACK TO THE CLINICAL TRIAL. SO I USED TO
10 BE A CEO OF A DRUG COMPANY. IF WE HAD A CLINICAL
11 TRIAL AND WE WERE READY TO GET IT STARTED, GET IT
12 INITIATED, WE COULDN'T WAIT 22 MONTHS TO DO THAT.
13 IT WOULD COST US MORE MONEY TO WAIT 22 MONTHS THAN
14 WE WOULD EVER GET FROM CIRM. SO THE FIRST THING IS
15 WE NEEDED TO HAVE THESE PROGRAMS AVAILABLE WHEN
16 THEY'RE NEEDED. THE SECOND THING IS THEY NEEDED TO
17 BE FASTER. SO WE CHECKED THOSE BOXES OFF.

18 WE NEEDED TO BE NOT OVERLY ONEROUS. THERE
19 WERE THINGS UNDER OUR PROGRAM, FOR EXAMPLE, OUR LOAN
20 PROGRAM. WE HAVE A LOAN PROGRAM, AND THE LOAN
21 PROGRAM HAD FORGIVABLE -- IT WAS A FORGIVABLE LOAN.
22 SO IF THE PROGRAM DIDN'T WORK, WE WOULD FORGIVE YOU
23 OF YOUR OBLIGATIONS UNDER THE LOAN. EXCEPT THE ONLY
24 PROBLEM WAS FOR AUDITING FIRMS, THEY DIDN'T SEE US
25 AS FORGIVING. SO HERE WOULD BE THIS COMPANY

BARRISTERS' REPORTING SERVICE

1 STRUGGLING, TRYING TO RAISE MONEY, LET'S SAY IT'S A
2 SMALL PUBLICLY TRADED COMPANY, WE GIVE A \$20 MILLION
3 LOAN, THE PROGRAM DIDN'T WORK, WE FORGAVE IT, THEY
4 STILL HAD TO CARRY \$20 MILLION OF DEBT THAT WE NEVER
5 EXPECT TO BE REPAID FOR ON THEIR BALANCE SHEET. SO
6 WE NEEDED TO CLEAR UP THINGS LIKE THAT.

7 AND THEN THE LAST THING IS WE NEED TO BE
8 CLEAR AND UNDERSTANDABLE. IF PEOPLE DON'T
9 UNDERSTAND OUR PROGRAM, THAT'S OUR FAULT. AND IF
10 THEY DON'T UNDERSTAND OUR PROGRAMS, THEN WE'RE NOT
11 GETTING THE MOST OUT OF IT.

12 THE SECOND THING THAT WE'RE DOING, AND
13 WE'RE DOING THIS RIGHT NOW, THIS IS A REAL -- THIS
14 ONE IS OUT THERE. WHAT WE KNOW IS WE HAVE A
15 TREMENDOUS AMOUNT OF TECHNOLOGY AT CIRM THAT CIRM
16 HAS FUNDED TO CREATE THAT'S UNPARTNERED. AND SO
17 WHAT WE'RE DOING HERE IS WE'RE TRYING TO INCENTIVIZE
18 THE FORMATION OF A COMPANY IN CALIFORNIA THAT WILL
19 SPECIALIZE IN STEM CELLS AND AGGREGATE THESE
20 TECHNOLOGIES AND SEND THEM OUT OF THE UNIVERSITY AND
21 ACTUALLY CREATE A COMPANY THAT CAN TAKE THEM PUBLIC.
22 SO APPLICATIONS FOR THIS ARE CURRENTLY BEING
23 ACCEPTED. WE'LL DO THE REVIEW FOR THIS PROGRAM IN
24 JANUARY. IF IT WORKS, IT WILL BE THE FIRST OF ITS
25 KIND EVER. SO STAY TUNED.

BARRISTERS' REPORTING SERVICE

1 THAT'S WHAT WE'RE DOING IN A NUTSHELL TO
2 TRY TO CREATE SOME DEMAND PULL ON OUR PROGRAM.

3 THE THIRD THING CENTERS AROUND THE HILL
4 THAT WE'RE TRYING TO PUSH. AND THAT'S THE
5 REGULATORY LANDSCAPE THAT WE HAVE. SO THE REALITY
6 OF THE CURRENT REGULATORY SYSTEM IS THIS. MOST
7 INVESTIGATORS, AND PARTICULARLY MOST INVESTIGATORS
8 THAT WE DEAL WITH ON THE ACADEMIC SIDE, SIMPLY DO
9 NOT HAVE THE EXPERIENCE NECESSARY TO NAVIGATE THE
10 REGULATORY SYSTEM FOR CELL THERAPY. CELL THERAPIES
11 ARE RELATIVELY NEW. THE REGULATIONS THEMSELVES ARE
12 VAGUE. NOT A LOT OF PEOPLE HAVE DONE IT. AND SO
13 THERE'S JUST A TREMENDOUS LACK OF EXPERIENCE, AND
14 THAT'S LEADING TO POINT TWO, WHICH IS THE
15 TRANSLATIONAL TIME AT EIGHT YEARS IS JUST
16 UNACCEPTABLY LONG WHEN A NON-CELL THERAPY MAKES THE
17 EXACT SAME JOURNEY IN ONLY 3.2 YEARS. SO WE NEED TO
18 FIX THAT.

19 THE CURRENT SYSTEM WE HAVE RIGHT NOW HAS
20 BEEN IN PLACE NOW FOR 15 YEARS, AND IT'S COMPLETELY
21 BINARY. IT EITHER SAYS YOU CAN COME TO MARKET
22 LEGALLY WITH A STEM CELL TWO WAYS. ONE WAY REQUIRES
23 ABSOLUTELY NO DATA ON THE SAFETY OR THE
24 EFFECTIVENESS OF YOUR TREATMENT. AND THEN THE OTHER
25 ONE TAKES LIKE TWO DECADES AND COSTS \$3 BILLION.

BARRISTERS' REPORTING SERVICE

1 AND THAT'S DRIVING POINT 4. AND POINT 4 IS WE'RE
2 SEEING A LOT OF WHAT WE DON'T WANT, WHICH IS THESE
3 UNREGULATED STEM CELL THERAPIES ENTERING THE MARKET
4 WITHOUT ANY DATA TO SUPPORT THEM, AND WE'RE SEEING
5 VERY LITTLE CELL THERAPIES MOVE THROUGH THE PATHWAY.

6 SO WE'RE DOING TWO THINGS ABOUT THIS. THE
7 FIRST IS, AND I'M PLEASED TO SAY THE BOARD, THANKS
8 TO J.T. AND HIS LEADERSHIP, JUST APPROVED WHAT WE
9 CALL THE PITCHING MACHINE. AND THE PITCHING MACHINE
10 IS DESIGNED TO FIT THIS LACK OF EXPERIENCE THAT
11 INVESTIGATORS HAVE IN THE TRANSLATIONAL PHASE OF
12 MEDICINE. WE CALL IT A PITCHING MACHINE BECAUSE
13 THERE ARE TWO ACTUAL CENTERS, PHYSICAL CENTERS, THAT
14 ARE DESIGNED TO WORK IN CONJUNCTION TO SPEED UP
15 TRANSLATIONAL RESEARCH AND HIT OUR GOAL OF MAKING
16 THAT TRANSLATIONAL TIME BE LESS THAN FOUR YEARS.

17 ONE IS THE TRANSLATING CENTER. THIS IS A
18 GROUP THAT DOES THE BORING, FDA-REQUIRED LABORATORY
19 WORK THAT FDA NEEDS IN ORDER TO CLEAR AN IND, THE
20 STUFF INVESTIGATORS DON'T LIKE TO DO AND DON'T WANT
21 TO DO AND DON'T HAVE EXPERIENCE DOING, THINGS LIKE
22 STABILITY STUDIES, CERTAIN KINDS OF TOXICOLOGY
23 STUDIES DONE EXACTLY THE WAY THE FDA WANTS THEM.

24 THE OTHER SIDE OF THIS IS WHAT WE CALL THE
25 ACCELERATING CENTER. THE ACCELERATING CENTER IS A

BARRISTERS' REPORTING SERVICE

1 FANCY WAY OF SAYING A STEM CELL-SPECIFIC CLINICAL
2 RESEARCH ORGANIZATION THAT WILL TAKE THE INFORMATION
3 FROM BOTH THE INVESTIGATOR AND FROM THE TRANSLATING
4 CENTER AND ACTUALLY WRITE AND COMPILE THE BLA FOR
5 THE INVESTIGATOR BECAUSE THEY'RE GOOD AT IT, THEY
6 LIKE DOING IT, THEY DO IT ALL THE TIME. QUINTILES
7 WON BOTH OF THESE AWARDS. THEY'RE THE LARGEST CRO
8 IN THE WORLD, AND THEY HAVE NOW COME TO CALIFORNIA.
9 AND IN THE STATE OF CALIFORNIA WE HAVE THE FIRST AND
10 ONLY PITCHING MACHINE WHICH I THINK IS GOING TO
11 BE -- I ACTUALLY THINK THIS MIGHT BE THE MOST
12 SIGNIFICANT PIECE OF INFRASTRUCTURE CIRM ENDS UP
13 ADDING. AND IT GOES ON AND IT'S NOT CIRM DEPENDENT.
14 SO THIS ENDS UP LIVING WITHOUT US. SO IF CIRM GOES
15 AWAY, THE PITCHING MACHINE STILL EXISTS IN
16 CALIFORNIA.

17 THE SECOND THING GOES TO THE BINARY
18 REGULATORY PARADIGM THAT WE HAVE, AND I MENTIONED
19 THIS. BUT BACK IN THE LATE '90S WHEN FDA WAS
20 INTRODUCING THE CURRENT REGULATORY SYSTEM THAT WE
21 HAVE, WHAT THEY PROPOSED WAS THIS TIERED APPROACH.
22 AND SO BASICALLY IT WAS THE MORE RISKY OR COMPLEX
23 YOUR CELL THERAPY WAS, THE MORE REGULATION WOULD BE
24 PLACED UPON IT. SEEMS TO MAKE PERFECT SENSE TO ME.
25 WHAT THEY ACTUALLY DELIVERED, THOUGH, WAS A BINARY

BARRISTERS' REPORTING SERVICE

1 APPROACH. SO THERE'S ESSENTIALLY NO REGULATION
2 REQUIRED UP UNTIL SOME CERTAIN TIPPING POINT. ONCE
3 YOU TRIP THAT THRESHOLD, YOU GO INTO A BLA, WHICH IS
4 THE MOST CUMBERSOME, ONEROUS REGULATORY PATHWAY THAT
5 EXISTS FOR ANYTHING ANYWHERE IN THE WORLD. THAT'S
6 THE DIFFERENCE.

7 THE PROBLEM WITH THIS BINARY SYSTEM IS IT
8 LEADS TO PREDICTABLY AREA THAT THEN ARE UNDER OR
9 OVERREGULATED, AND NEITHER ONE OF THESE ARE GOOD.
10 AND MORE IMPORTANTLY, WHAT IT REALLY DOES IS IT'S
11 DRIVING -- THE ONLY PLACE ON THIS GRAPH YOU REALLY
12 WANT TO BE IS WHERE THAT STAR IS. SO AS RISKY OR AS
13 COMPLEX A THERAPIES YOU CAN HAVE BEFORE YOU TRIP
14 REGULATION. SO YOU SHOW THIS TO SOME ECONOMIST,
15 THIS REGULATION, AND THEY WOULD PREDICT THAT THIS IS
16 WHAT WOULD HAPPEN. WELL, EARLIER THIS YEAR A STUDY
17 CAME OUT THAT SAID THAT'S EXACTLY WHAT'S HAPPENING.
18 SO WE'VE HAD ZERO, ZERO THINGS GO THROUGH THE
19 UP-REGULATED PATHWAY, NOT ONE IN 15 YEARS.

20 BUT WE HAVE SOMETHING LIKE 560 THERAPIES
21 BEING OFFERED, INCLUDING IN THE STATE OF CALIFORNIA,
22 FOR TREATMENTS WHERE THEY HAVE ESSENTIALLY NO DATA,
23 NO EFFICACY, NO SAFETY DATA TO SHOW THAT THEY'RE
24 USEFUL. AND THAT'S BECAUSE THAT'S THE SYSTEM THAT
25 WAS CREATED.

BARRISTERS' REPORTING SERVICE

1 AND SO WHAT WE'RE TRYING TO DO IS WORK
2 WITH THE FDA TO SAY, HEY, LOOK, IF YOU GO BACK AND
3 ACTUALLY FINISH WHAT YOU STARTED AND DO WHAT YOU
4 SAID YOU'D DO, IT WILL HELP US MOVE THIS FIELD
5 ALONG. LET'S CREATE A PATHWAY THAT'S PRACTICAL,
6 THAT PHYSICIANS AND OTHERS CAN COMPLY WITH THAT
7 CREATES SOME LEVEL OF SAFETY AND EFFICACY STANDARDS
8 THAT CURRENTLY DON'T EXIST. AND THE FDA HAS BEEN
9 GREAT WITH THIS. I'VE ACTUALLY MET WITH
10 COMMISSIONER CALIFF. I'VE PRESENTED IN FRONT OF
11 FDA. I'VE MET WITH THEIR PEOPLE AT CBER A NUMBER OF
12 TIMES TALKING ABOUT HOW WE CAN WORK TOGETHER ON
13 THIS. CERTAINLY WE'VE SPENT A LOT OF MONEY AND MADE
14 A LOT OF INVESTMENT WITH THE PITCHING MACHINE, WHICH
15 SHOULD ACTUALLY MAKE FDA'S LIFE EASIER. AND SO WE
16 WANT TO DO WHAT WE CAN TO HELP THEM WITH THIS ISSUE
17 TOO.

18 SO THAT'S OUR STRATEGY: PUSH, PULL, AND
19 LEVEL. FAIRLY EASY TO REMEMBER.

20 ONE OF THE THINGS I SAID IS THIS PLAN IS
21 NOTHING IF IT DOESN'T HAVE OBJECTIVE MEASURES OF
22 SUCCESS. AND IT DOES, AND THEY ARE AUDACIOUS, THEY
23 ARE STRETCH GOALS. WHEN WE LAID THEM OUT, I THINK
24 THERE WAS AN AUDIBLE GULP AMONG THE TEAM, THAT YOU
25 HAD TO COME UP WITH THESE, BUT NOW THEY'RE GETTING

BARRISTERS' REPORTING SERVICE

1 THE HANG OF IT. I WOULDN'T WANT TO SAY THEIR
2 ARROGANT, BUT THEY'VE GOT A LITTLE SWAGGER ABOUT
3 THEM. I THINK THEY FEEL LIKE THEY'RE GOING TO
4 ACHIEVE THESE. LET'S GO THROUGH THEM QUICKLY.

5 FIFTY NEW CANDIDATES OF DISCOVERY. SO 50
6 NEW THINGS OVER THE NEXT FIVE YEARS WE'RE GOING TO
7 COME UP WITH. WE HAVE THESE THINGS CALLED
8 PROGRESSION EVENTS. SO IF WE HAVE AN EARLY STAGE
9 AWARD, LET'S SAY A DISCOVERY STAGE AWARD, IF THAT
10 GOES SUCCESSFULLY TO A TRANSLATIONAL AWARD, IF A
11 TRANSLATIONAL AWARD LEADS SUCCESSFULLY TO A CLINICAL
12 TRIAL, WE CALL THAT A PROGRESSION EVENT. THAT'S A
13 GREAT THING FOR US. WE'RE GOING TO INCREASE
14 PROGRESSION EVENTS BY 50 PERCENT. AND I'LL TELL YOU
15 THE PUNCHLINE IS WE JUST FOUND OUT YESTERDAY WE'RE
16 ALREADY AT 34 -- WE'RE ALREADY UP 34 PERCENT. WE
17 WANT TO GET TO 50. SO WE'RE ALREADY UP 34 PERCENT.
18 WE'RE EXCITED ABOUT THAT.

19 WE WANT TO WORK WITH FDA TO ENACT A NEW,
20 MORE EFFICIENT REGULATORY PARADIGM THAT ACHIEVES THE
21 GOALS.

22 WE WANT TO REDUCE THAT TRANSLATIONAL TIME
23 BY 50 PERCENT. SO THAT'S THE EIGHT YEARS DOWN TO
24 FOUR.

25 HERE'S THE BIG ONE. FIFTY NEW CLINICAL

BARRISTERS' REPORTING SERVICE

1 TRIALS. WE THOUGHT, OH, MY GOODNESS, 50 NEW
2 CLINICAL TRIALS. IN THE FIRST 12 YEARS WE HAD TEN.
3 WE'RE GOING TO ADD 50. WE'RE GOING TO ADD MORE THAN
4 TEN JUST THIS YEAR. SO WE FEEL VERY GOOD ABOUT
5 THIS.

6 AND THEN THE LAST THING IS WE WANT TO HAVE
7 THOSE PROGRAMS, THOSE CLINICAL PROGRAMS, THAT ARE
8 SUCCESSFUL, WE WANT TO HAVE THEM GET PARTNERED UP
9 WITH INDUSTRY SO THEY CAN GO ON AND BE SELF-FUNDING
10 AND NOT REQUIRE CIRM ANYMORE. SO 50 PERCENT OF OUR
11 CLINICAL PROGRAMS BE PARTNERED BEFORE THEY LEAVE.

12 SO THESE ARE VERY REAL. WE'RE GOING TO
13 KNOW AT 2020 WHETHER OR NOT WE HIT THESE OR NOT, BUT
14 I'M GOING TO TELL YOU, WITH THE TEAM I HAVE, I
15 WOULDN'T BET AGAINST US. OKAY.

16 WITH THAT SAID, THERE ARE THINGS THAT ARE
17 RISKS TO THIS PLAN, FOR SURE. FIRST IS THERE MIGHT
18 JUST -- WE WANT 50 CLINICAL TRIALS. THERE MIGHT
19 JUST NOT BE 50 GOOD THINGS TO FUND OUT THERE. AND
20 WE WON'T LOWER OUR QUALITY STANDARDS, FOR SURE.
21 THERE MIGHT BE -- FROM AN INDUSTRY STANDPOINT, THEY
22 MIGHT JUST CONTINUE TO NOT HAVE ENOUGH INTEREST IN
23 US. THAT'S CERTAINLY A POSSIBILITY. THE FACT THAT
24 WE HAVE A LIMITED LIFE AS AN AGENCY, EVEN THOUGH
25 IT'S A LOT LONGER THAN WE ORIGINALLY THOUGHT, BUT

BARRISTERS' REPORTING SERVICE

1 THE FACT THAT WE HAVE A LIMITED LIFE COULD LIMIT OUR
2 ABILITY TO ATTRACT AND RETAIN TOP QUALITY PEOPLE.
3 I'LL TELL YOU WE'RE NOT SEEING THAT NOW.

4 INVESTORS MIGHT BE UNINTERESTED. AND
5 THEN, LAST, FDA JUST MIGHT BE UNWILLING TO CHANGE.
6 CERTAINLY A POSSIBILITY.

7 ONE OTHER COMMENT I WANT TO MAKE HERE. WE
8 KNOW WE CALL IT 2.0, BUT THIS IS BOTH TO SHOW YOU
9 AND A PROMISE TO YOU. 2.0 IS REALLY MORE LIKE 2.8
10 ALREADY. SO WE LAUNCHED IT. IT WASN'T PERFECT. WE
11 KNOW IT WASN'T PERFECT. AND SO OUR COMMITMENT TO
12 YOU AND TO THE BOARD IS TO ALWAYS BE VERY
13 SELF-EFFACED AND LOOK AT WHAT WE'RE DOING AND
14 OBJECTIVELY, WHEN WE SEE SOMETHING THAT'S NOT
15 WORKING OR SEE SOMETHING WE DIDN'T GET RIGHT, JUST
16 MAKE IT BETTER. OUR ULTIMATE SUCCESS IS JUDGED BY
17 WHETHER OR NOT WE HIT THE MISSION, NOT WHETHER OR
18 NOT WE GET EVERYTHING RIGHT ON THE FIRST LAUNCH. SO
19 THERE'S JUST A NUMBER OF MODIFICATIONS WE'VE ALREADY
20 MADE TO THE SYSTEM.

21 WE CHANGED THE SCORING SYSTEM. WE'VE
22 ACTUALLY ADDED PROCESSES TO MAKE SURE THAT THE
23 REVIEW IS FAIR. SOMETIMES WE GET CRITICIZED BECAUSE
24 WE HAVE TO HAVE OUR REVIEWS DONE BEHIND CLOSED
25 DOORS, THAT THERE MIGHT BE A LACK OF FAIRNESS

BARRISTERS' REPORTING SERVICE

1 ASSOCIATED WITH THAT. SO WE TRY TO ADDRESS SOME OF
2 THOSE ISSUES. WE REMOVED INDIRECTS FOR FOR-PROFITS
3 BECAUSE WE JUST DIDN'T THINK THEY NEEDED IT. AND
4 SURE ENOUGH, WE HAVEN'T SEEN A REDUCTION IN OUR
5 AWARDS EVEN THOUGH WE'VE TAKEN THAT COST OUT. AND
6 WE ESTABLISHED MILESTONES FOR DISC AND TRANS
7 PROGRAMS. BUT THE POINT OF THIS SLIDE IS TO SAY
8 THAT WE KNOW WE'RE NOT PERFECT, AND OUR COMMITMENT
9 IS THAT WE WILL CONTINUALLY GET THERE.

10 AND THEN THE LAST THING I WANT TO END ON
11 IS THE WHY BEHIND WHAT'S GOING ON HERE. THERE HAS
12 BEEN -- TO SAY THERE HAS BEEN A SIGNIFICANT CHANGE
13 IN CIRM WOULD BE TO SAY, LIKE, DURING THE LOMA
14 PRIETO EARTHQUAKE, THE GROUND SHOOK A LITTLE. THE
15 CHANGE HAS BEEN ABSOLUTELY MASSIVE, AND THIS TEAM
16 HAS GOTTEN HOLD OF IT. THEY'RE EMBRACING THAT
17 CHANGE. THE ENTIRE GROUP, THE BOARD, THE PATIENT
18 ADVOCATES, THE MANAGEMENT, THE TEAM ITSELF ARE ALL
19 ALIGNING AROUND THE MISSION. THERE'S TREMENDOUS
20 OWNERSHIP AROUND THESE GOALS. I'LL SAY THIS.

21 MY FAVORITE STORY IS WHEN WE LAUNCHED CIRM
22 2.0, WE WANTED TO LAUNCH IT BY JANUARY 1ST, AND IT
23 DIDN'T MATTER WHEN ON JANUARY 1ST. IT COULD HAVE
24 BEEN ANY TIME ON JANUARY 1ST. AND THERE WAS A GROUP
25 OF PEOPLE THERE DECEMBER 31ST, NEW YEAR'S EVE, THAT

BARRISTERS' REPORTING SERVICE

1 THEY WERE NOT GOING TO LAUNCH THAT JANUARY 1ST.
2 THEY STAYED THERE ON NEW YEAR'S EVE TO GET THAT
3 THING OUT SO THEY COULD SAY THEY GOT IT OUT. AND
4 THAT'S THIS GROUP OF PEOPLE WE HAVE. THEY OWN THEIR
5 GOALS. AND A LOT OF TIMES PEOPLE JUST SAY I HAD A
6 GREAT TEAM, I HAD A GREAT TEAM. I HAVE A GREAT
7 TEAM, BUT MORE IMPORTANTLY, I CAN PROVE IT. I CAN
8 PROVE I HAVE A GREAT TEAM BECAUSE I CAN SHOW YOU
9 THOSE PERFORMANCE NUMBERS, I CAN SHOW YOU
10 PRODUCTIVITY, I CAN SHOW YOU EFFICIENCY, I CAN SHOW
11 YOU QUALITY. AND I'M JUST VERY -- I'M VERY, VERY
12 HONORED, I'M VERY BLESSED TO GET TO WORK WITH THEM
13 AND VERY THANKFUL FOR EVERYTHING THEY DO.
14 FORTUNATELY, WE WON'T TELL THEM THAT, RIGHT. NO.
15 THEY'RE GREAT.

16 THAT'S WHAT I GOT, PUSH, PULL, LEVEL.
17 I'LL BE HAPPY TO TAKE ANY AND ALL QUESTIONS.

18 CHAIRPERSON YEE: THANK YOU VERY MUCH,
19 DR. MILLS. QUESTIONS BY MEMBERS? COMMENTS?

20 DR. SADANA: MY QUESTION, YOU MENTIONED
21 ABOUT IMPEDIMENT, AND WERE YOU ALLUDING TO A VARIETY
22 OF STEM CELLS?

23 DR. MILLS: I'M SORRY. ONE MORE TIME.

24 DR. SADANA: YOU MENTIONED ABOUT
25 IMPEDIMENT IN PROGRESSING DEVELOPMENT AT ONE POINT.

BARRISTERS' REPORTING SERVICE

1 WHAT WAS IT REALLY THE IMPEDIMENT?

2 DR. MILLS: WITH THE REGULATORY SYSTEM?

3 DR. SADANA: YES.

4 DR. MILLS: YEAH. SO THAT WAS REALLY JUST
5 GOING TO THAT OUR REGULATORY SYSTEM ISN'T
6 INCENTIVIZING THE OUTCOME THAT WE WANT. WE'RE
7 GETTING -- IT'S ACTUALLY -- AND EVEN THE FDA DOESN'T
8 WANT IT. AND SO WE DID A SURVEY ACTUALLY, AND THIS
9 WAS ONE OF THE FIRST ALARM BELLS THAT STARTED GOING
10 OFF. WHEN WE WERE DOING OUR ROADSHOWS, WE ALSO DID
11 SURVEYS, WE TALKED WITH EVERYONE WE COULD. WHEN WE
12 DID OUR SURVEY, BY FAR, WE ASKED THE QUESTION OF THE
13 SINGLE BASE IMPEDIMENT TO DEVELOPING A STEM CELL
14 THERAPY TODAY. THIS IS THE STATE OF CALIFORNIA.
15 PROPOSITION 71 CAME. YOU WOULD HAVE THOUGHT IT
16 WOULD HAVE BEEN REGULATION OR INABILITY TO HAVE
17 ACCESS TO CELLS OR SOMETHING LIKE THAT. NO. FDA.
18 70 PERCENT OF RESPONDENTS LISTED FDA AS THEIR SINGLE
19 BASE. AND IT DIDN'T MATTER WHETHER IT WAS THE
20 PATIENTS OR THE COMPANIES OR THE ACADEMIC
21 INVESTIGATORS. IT WAS ACROSS THE BOARD.

22 NOW, AGAIN, I DON'T THINK THAT'S ALL ON
23 FDA. FDA HAS GOT A SYSTEM, AND THAT SYSTEM HAS GOT
24 SOME PROBLEMS WITH IT. BUT I KNOW FROM FDA'S
25 STANDPOINT, THERE'S A TREMENDOUS AMOUNT OF

BARRISTERS' REPORTING SERVICE

1 FRUSTRATION TOO BECAUSE WE HAVE INVESTIGATORS THAT
2 HAVE ABSOLUTELY NO EXPERIENCE NAVIGATING THIS AREA
3 TRYING TO NAVIGATE THIS AREA, AND THAT'S WHY WE PUT
4 IN THAT ACCELERATING AND TRANSLATING CENTER. SO WE
5 COULD GIVE THEM THE HELP.

6 CHAIRPERSON YEE: ANOTHER QUESTION?

7 DR. QUICK: DR. MILLS, THANK YOU SO MUCH.
8 CONGRATULATIONS TO YOU AND YOUR TEAM FOR ALL YOUR
9 SUCCESSES.

10 QUESTIONS. SO IF CIRM WAS TO GO OUT OF
11 BUSINESS TODAY, I KNOW YOU ARE DOING A GREAT JOB
12 MANAGING IT TO MAKE IT LAST AS LONG AS POSSIBLE,
13 WHAT'S THE BEST STORY RELATED TO YOUR MISSION THAT
14 YOU FEEL YOU HAVE TO TELL RIGHT NOW?

15 DR. MILLS: IT'S A GREAT QUESTION. I
16 WOULD HATE FOR IT TO END RIGHT NOW BECAUSE THE
17 ENGINE IS JUST STARTING UP. AND, YOU KNOW, THE REAL
18 STORY ISN'T GOING TO BE ONE-OFF. THE REAL STORY IS
19 GOING TO BE A CONTINUUM OF SUCCESS. AND THAT IS
20 GOING TO BECOME MORE AND MORE APPARENT TO PEOPLE. I
21 CAN SEE IT NOW BECAUSE I'M INSIDE IT. I LIVE IT
22 EVERY DAY. BUT IT'S NOT COMPLETELY APPARENT ON THE
23 OUTSIDE. BUT IF YOU'LL HOLD THAT UNTIL THE CLINICAL
24 PRESENTATION, I'LL SHOW YOU.

25 DR. QUICK: OKAY. GREAT. THANK YOU.

BARRISTERS' REPORTING SERVICE

1 IN TERMS OF -- SO THAT'S ON SORT OF A
2 SCIENCE AND THE OUTCOMES MISSION. WOULD YOU SAY
3 THAT THE PITCHING MACHINE IS THE BEST SORT OF
4 OPERATIONAL SUCCESS FOR CIRM TO DATE?

5 DR. MILLS: WELL, I THINK IT'S THE ONE
6 THAT HAS THE MOST PROMISE FROM THE INFRASTRUCTURE
7 STANDPOINT. JAMES AND I WERE TALKING THE OTHER DAY
8 ABOUT HOW WE WISHED WE HAD THAT FIVE YEARS AGO.
9 INTERESTINGLY, I USED TO BE -- BEFORE I WAS
10 PRESIDENT OF CIRM, I USED TO BE A REVIEWER.
11 REVIEWERS ARE REQUIRED TO BE EXTERNAL TO THE STATE
12 OF CALIFORNIA, AND I LIVED IN MARYLAND. AND SO I
13 WOULD REVIEW ALL OF THESE PROGRAMS FOR CIRM. AND IT
14 WAS SUCH A CONSISTENT THEME, THAT IT WAS ALMOST LIKE
15 A STANDARD NOTE WE WOULD MAKE, LIKE THE INVESTIGATOR
16 DOESN'T UNDERSTAND THE REGULATORY SYSTEM. AND THE
17 ANALOGY I USE IS LIKE WE KNEW WE FISH, BUT WE WERE
18 DEMANDING THEY TAKE FLYING LESSONS WHEN THERE ARE
19 PEOPLE THAT JUST DO THAT STUFF FOR A LIVING. AND SO
20 I THINK IT HAS THE ABILITY TO HAVE THE GREATEST
21 LONG-TERM POTENTIAL IMPACT AND CONTINUOUSLY
22 ACCELERATE IT, BUT IT'S JUST LAUNCHED. SO I DON'T
23 WANT TO -- I LIKE ITS PROMISE. LET'S SEE IT
24 DELIVER.

25 DR. QUICK: SO OBVIOUSLY WE ALL -- I'M A

BARRISTERS' REPORTING SERVICE

1 SCIENTIST. YOU KNOW, THE LONG-TERM CLINICAL
2 OUTCOMES BECAUSE OF CIRM ARE FOREMOST THE MOST
3 IMPORTANT THING, BUT HAVE YOU DONE AN ANALYSIS OF
4 WORKFORCE IMPACT, SORT OF ECONOMIC DEVELOPMENT
5 IMPACT THAT CIRM HAS DONE? AND THEN, FINALLY, ON A
6 SLIGHTLY DIFFERENT LEVEL, HAVE YOU LOOKED AT HOW
7 CIRM DOLLARS HAVE LEVERAGED OTHER DOLLARS
8 THROUGHOUT, WHETHER IT'S NIH DOLLARS OR NSF DOLLARS,
9 TO CONTINUE TO MAKE THE CASE THAT THESE INITIAL
10 INVESTMENTS HAVE HAD IMPACT FAR AND WIDE?

11 DR. MILLS: SINCE I'VE BEEN HERE, WE
12 HAVEN'T REDONE THE ECONOMIC IMPACT. I KNOW
13 PREVIOUSLY IT HAD BEEN DONE. I'M A BIG BELIEVER IN
14 FOCUS ON THE THING YOU WANT, AND THE REST OF IT WILL
15 COME ALONG. I DO KNOW, THOUGH, OUR FOLLOW-ON
16 FUNDING NUMBER. SO THE LEVERAGING NUMBER. SO IT'S
17 SOMETHING LIKE 2.1 BILLION DISBURSED. SO ON THAT
18 2.1 BILLION, I'M JUST PRAYING I GET IT RIGHT, ON THE
19 2.1 BILLION DISBURSED, WE'VE LEVERAGED AN ADDITIONAL
20 1.35 BILLION ON OUR RECURRING PROGRAMS AND THEN
21 ANOTHER 110 MILLION ON OUR ALPHA CLINICS. SO ABOUT
22 1.5 BILLION.

23 DR. QUICK: GREAT. THANK YOU SO MUCH.

24 CHAIRMAN THOMAS: HI. THIS IS JON THOMAS.
25 NICE TO SEE EVERYBODY. THANK YOU VERY MUCH FOR

BARRISTERS' REPORTING SERVICE

1 HEARING OUR STORY. WE APPRECIATE IT.

2 ONE POINT IN TERMS OF WORKFORCE, I THINK,
3 THAT'S AN INTERESTING METRIC. AND MAYBE, RANDY, YOU
4 KNOW THE UPDATED NUMBER ON THIS. BECAUSE CIRM HAS
5 OFFERED THE POSSIBILITY OF FUNDING FOR STEM
6 CELL-RELATED THERAPIES, WE'VE OVER THE YEARS HAD A
7 GREAT MANY SENIOR SCIENTISTS ACTUALLY MOVE TO
8 CALIFORNIA BRINGING WITH THEM THEIR POST DOCS AND
9 TEAMS AND MULTIPLIER EFFECTS AND ALL THAT SORT OF
10 THING. AND I THINK -- DO YOU KNOW WHAT THAT NUMBER
11 IS, RANDY?

12 DR. MILLS: ABSOLUTELY NO IDEA.

13 CHAIRMAN THOMAS: SO THE NUMBER -- I DON'T
14 THINK WE HAVE AN UPDATED ONE, BUT THE NUMBER THAT WE
15 OPERATED ON A COUPLE YEARS AGO WAS, I THINK, 200,
16 GIVE OR TAKE. I KNOW THAT THAT HAS INCREASED. SO
17 THERE'S BEEN A MATERIAL MOVEMENT OF VERY HIGHLY
18 PLACED PERSONNEL IN THE FIELD WHO HAVE COME TO HAVE
19 THE POSSIBILITY OF APPLYING TO CIRM FOR FUNDING.
20 WE'LL GET THE UPDATED NUMBER BACK TO YOU ON THAT.

21 DR. MILLS: ON THE OBJECTIVE MEASURES OF
22 SUCCESS, SO YOU CAN TELL WE MEASURE EVERYTHING WE
23 CAN MEASURE. AND OUR CHALLENGE BECOMES WHAT WE CAN
24 REFERENCE OFF OF TO KNOW. SO WHAT I CAN POINT TO
25 ARE OUR CLINICAL TRIAL PROGRAMS HITTING ON-TIME

BARRISTERS' REPORTING SERVICE

1 MILESTONE AT 77 PERCENT IS LIKE VASTLY MORE
2 SUCCESSFUL THAN FEDERAL FUNDING. IT'S PUBLISHED ON
3 FEDERAL FUNDING. SO FOR TRIALS NIH FUNDS, ONLY A
4 THIRD OF THEM HIT THEIR MILESTONES ON TIME. THE
5 AVERAGE IS TWICE AS LONG AS THEY ORIGINALLY SAID,
6 AND 10 PERCENT OF THEM NEVER ENROLL A SINGLE
7 PATIENT. SO WE HAVE NONE IN THE LAST CATEGORY, AND
8 OUR TRIALS ARE 60 -- OR 77 PERCENT ARE ON TIME. SO
9 WE'RE AT LEAST TWICE AS FAST AS THE FEDERAL
10 GOVERNMENT.

11 CHAIRPERSON YEE: THANK YOU. I'VE GOT A
12 COUPLE QUESTIONS. ONE, THANK YOU FOR THE
13 PRESENTATION. JUST THE ACCELERATION OF ACTIVITY
14 SINCE OUR LAST COMMITTEE'S CONVENING IS REMARKABLE.

15 JUST ON THE QUESTION OF METRICS. I THINK,
16 AS YOU'VE PRESENTED, ALL OF THE STRATEGIC PLAN
17 PARTNERSHIP INITIATIVES, I'M JUST CURIOUS FROM A
18 POLICYMAKER STANDPOINT, WHEN WE'RE MAKING THE CASE
19 OR TRYING TO DEMONSTRATE THE IMPACT ON THE PUBLIC
20 INVESTMENT, THE TYPES OF METRICS THAT WE OUGHT TO BE
21 THINKING ABOUT RELATIVE TO THE PARTNERSHIP MISSION
22 AND ESPECIALLY THINGS LIKE THE ACCELERATING CENTER,
23 WHICH IS HEAVILY FUNDED, BUT HOW OUGHT WE LOOK AT, I
24 GUESS, HOW WE MEASURE THE IMPACT OF THAT?

25 DR. MILLS: SO I THINK FIRST IN OUR

BARRISTERS' REPORTING SERVICE

1 HISTORY WE GOT A LITTLE CONFUSED, THAT SOMEHOW THAT
2 THIS COULD BE A MONEY-MAKING DIRECTLY VENTURE FOR
3 CIRM. IF IT WERE, CIRM WOULDN'T NEED TO EXIST. IF
4 YOU COULD GO INTO THE PRIVATE MARKETS AND GET THIS
5 KIND OF CAPITAL AND GET A RETURN ON IT, WE WOULD BE
6 FINE. SO WE UNDERSTAND THERE'S A RISK PROFILE
7 ASSOCIATED WITH WHAT WE DO THAT'S JUST HIGHER THAN
8 WHAT YOU COULD NORMALLY MAKE MONEY OFF OF.

9 WITH THAT SAID, I THINK WE'VE GOTTEN
10 SMARTER ABOUT HOW WE SET SOME OF THIS STUFF UP. SO
11 THE ACCELERATING AND THE TRANSLATING CENTER, FOR
12 EXAMPLE, THOSE ARE PROGRAMS THAT WE HAVE WHERE WE'RE
13 MAKING AN UPFRONT INVESTMENT IN. BUT THE WAY WE
14 MAKE THOSE INVESTMENTS AND WE PAY THOSE AWARDS OUT
15 ACTUALLY DICTATE THAT THEY WILL MAKE MONEY FOR US.
16 SO ON THOSE PROGRAMS, BECAUSE WHAT WE'RE DOING IS WE
17 INCENTIVIZED QUINTILES TO OPEN UP A COMPANY
18 SPECIFICALLY IN CALIFORNIA TO DO EXACTLY WHAT WE
19 WANTED TO DO, BUT THEY'RE GOING TO MAKE MONEY OFF OF
20 THAT. SO THE WAY WE STRUCTURED THE AWARD WAS THAT
21 WE ACTUALLY GET OUR RETURN TO US BEFORE THAT AWARD
22 EVEN GETS PAID OUT.

23 SO JUST TO GIVE YOU AN EXAMPLE ON THE
24 ACCELERATING CENTER, WE WILL MAKE A TOTAL OF A \$15
25 MILLION INVESTMENT IF THAT THING IS FULLY

BARRISTERS' REPORTING SERVICE

1 SUCCESSFUL; BUT IF IT'S FULLY SUCCESSFUL, WE WILL
2 HAVE RETURNED TO US \$22.5 MILLION. SO THERE'S VERY
3 FEW THINGS WE HAVE GOING ON THAT -- AND THAT'S IN
4 FIVE YEARS. THAT'S NOT LIKE FOREVER MONEY. IN OUR
5 LIFETIME AT CIRM, WE WILL GET A \$22.5 MILLION RETURN
6 ON A \$15 MILLION INVESTMENT. SO WE STILL GOT
7 EXACTLY WHAT WE WANT. SO WE'RE DOING THOSE KINDS OF
8 THINGS.

9 WITH REGARDS TO THE PARTNERING, OUR ATP3
10 PROGRAM, WE'VE ACTUALLY STRUCTURED THAT IN THE FORM
11 OF FORGIVABLE DEBT. WE CAN'T OWN EQUITY IN
12 SOMETHING. WE WOULD LIKE TO. THAT WAS MY FIRST
13 CHOICE IS LET'S JUST OWN THE INVESTMENTS. HAVE THIS
14 COMPANY TAKE IT PUBLIC AND CIRM BE FUNDED FOR A LONG
15 TIME. THEN JAMES SAID NO. AND SO WE STRUCTURED IT
16 AS CONVERTIBLE DEBT TO TRY TO BASICALLY GET TO THE
17 SAME APPROACH WHERE WE CAN MAKE INVESTMENTS IN THIS
18 THING AND HAVE, INSTEAD OF A PRODUCT, WE ACTUALLY
19 HAVE A COMPANY. WE ACTUALLY OWN -- WE DON'T OWN,
20 BUT WE HAVE THE RIGHT TO CALL A REPAYMENT A LOT MORE
21 ASSURED THAN ANOTHER MIGHT BE. SO WE'RE TRYING TO
22 STRUCTURE THINGS.

23 CHAIRPERSON YEE: OKAY. THAT'S HELPFUL.

24 AND THEN WITH RESPECT TO ANY STEPS THAT
25 YOU'RE TAKING IN TERMS OF INCREASING THE INDUSTRY

BARRISTERS' REPORTING SERVICE

1 PARTICIPATION. OBVIOUSLY IT'S CRITICAL TO LATER
2 STAGES. IS THERE ANY SPECIFIC STEPS?

3 DR. MILLS: WELL, SO THOSE THINGS THAT
4 I -- I THINK THE BIGGEST THING FOR US TO DO WAS TO
5 BE EASIER TO WORK WITH. SO THOSE FOUR, FREQUENT,
6 FASTER, ACCELERATING, AND CLEAR HAVE HELPED A LOT.
7 BUT WHEN I COME BACK TO YOU NEXT YEAR, I'LL ACTUALLY
8 BE ABLE TO HAVE REAL HARD STATISTICS. INDUSTRY
9 ENGAGEMENT IS GOING UP. WE KNOW THAT, PARTICULARLY
10 IN THE CLINICAL STAGE PROGRAMS. IT'S KIND OF EARLY
11 YET TO TELL.

12 THE OTHER THING WE DID WAS WE ACTUALLY
13 COMPLETELY RESTRUCTURED OUR LOAN PROGRAM. WHEN YOU
14 HAD A LOAN IN THE GRANT PROGRAM, TOGETHER THOSE WERE
15 KIND OF LIKE THE WORST OF BOTH WORLDS. A COMPANY
16 COULD EITHER HAVE A GRANT AND HAVE ROYALTY
17 ENTANGLEMENTS, AND LARGE COMPANIES DON'T LIKE, THAT
18 ARE LOOKING TO ACQUIRE SMALL COMPANIES, DON'T LIKE
19 ROYALTY ENTANGLEMENTS. ON THE OTHER HAND, THEY
20 WOULD HAVE IT AS DEBT AND THE BALANCE SHEET ISSUE.
21 THEY DIDN'T LIKE THAT. SO ACTUALLY JAMES GAVE US A
22 BRILLIANT CONCEPT OF, WELL, WE CAN JUST LET THEM
23 ELECT THAT DOWN THE ROAD. THEY DON'T HAVE TO DECIDE
24 NOW. SO IT EXISTS IN TWO STATES. IF YOU DON'T LIKE
25 ROYALTY ENTANGLEMENTS, IT'S A LOAN. IF YOU DON'T

BARRISTERS' REPORTING SERVICE

1 LIKE DEBT, IT'S A GRANT. SO EXAMPLES. IT SEEMS TO
2 BE WORKING.

3 CHAIRPERSON YEE: GOOD. GOOD.

4 AND THEN, FINALLY, ON YOUR PRESENTATION,
5 SO THE ROLE OF PATIENTS. I'M OBVIOUSLY LOOKING AT
6 THE ULTIMATE BENEFICIARIES OF ALL THIS WORK. IS
7 THERE A ROLE FOR PATIENT ADVOCATES WITH RESPECT TO
8 THE CIRM 2.0 ENVIRONMENT? I'M THINKING PARTICULARLY
9 WITH RESPECT TO THE REGULATORY HURDLES.

10 DR. MILLS: WE HAVE MADE THE PATIENT
11 ADVOCATES WORK. THE PATIENT ADVOCATES, WHEN WE WENT
12 AROUND AND DID THE ROADSHOW, THEY WANTED A MORE
13 ACTIVE ROLE. THEY HAVE A MORE ACTIVE ROLE AT CIRM
14 NOW. SO OUR GWG, AN EXAMPLE, SEVEN PATIENT
15 ADVOCATES ON THEM, THEY'RE MEETING, WE WILL HOLD 20
16 GWG REVIEWS THIS YEAR ALONE. SO THAT'S A LOT MORE
17 WORK. BUT WE'VE ALSO -- THEY USED TO, IN ESSENCE,
18 IN THOSE ROLES BE SPECTATORS. THEY WOULD SIT AT THE
19 TABLE AND OBSERVE. WELL, SOME OF THEM ARE JUST
20 BRILLIANT AND INTERESTED AND AFFECTED PARTIES. AND
21 SO WE ACTUALLY GAVE THEM -- EVERY TIME WE DO A
22 REVIEW OF A CLINICAL PROGRAM, A PATIENT ADVOCATE IS
23 ONE OF OUR REVIEWERS, ACTUALLY HAS TO DO THE REVIEW,
24 COMMENT ON IT AND ALL THAT OTHER STUFF. AND SO
25 THAT'S HELPED A LOT. SO THEY'RE A LOT MORE ACTIVE

BARRISTERS' REPORTING SERVICE

1 ON THE FRONT END OF THE WORK.

2 SECOND THING WE DID WAS WE CREATED FOR OUR
3 PROGRAMS WHAT WE CALL CLINICAL ADVISORY PANEL, CAPS.
4 WE USED TO HAVE A VERSION OF THIS, WE'D HOLD IT
5 ABOUT EVERY 18 MONTHS. WE'D INVITE OUR CLINICAL
6 PROGRAM IN, AND WE'D SORT OF READ THEM THE RIOT ACT
7 FOR WHY THEY'RE NOT HITTING THE MILESTONES. IT
8 WASN'T PARTICULARLY HELPFUL. HERE WHAT WE'VE DONE,
9 AND PATIENT ADVOCATES HAD NO ROLE IN THAT, SO HERE
10 WHAT WE'VE DONE IS WE'VE SAID, OKAY, WE'RE GOING TO
11 CREATE, EVERY TIME WE START A CLINICAL AWARD FROM
12 CIRM, WE'RE GOING TO PUT TOGETHER BASICALLY AN
13 ADVISORY PANEL. AND THEN ADVISORY PANELS WOULD HAVE
14 A COUPLE OF PEOPLE FROM CIRM, IT'S GOING TO HAVE A
15 COUPLE OF EXTERNAL EXPERTS ON WHATEVER THE
16 PARTICULAR CHALLENGE IS THAT MIGHT BE ASSOCIATED
17 WITH THAT PROGRAM, IT'S GOING TO HAVE AT LEAST ONE
18 PERSON DIRECTLY AFFECTED BY THAT DISEASE ON THAT.

19 AND WE SET IT UP. SO EVERY ONE OF THESE
20 TRIALS WE HAVE THIS CAP. THESE CAPS MEET, NOT EVERY
21 18 MONTHS, THEY MEET QUARTERLY. SO THEY CAN PROVIDE
22 VERY REAL-TIME HELP TO THE INVESTIGATOR ON HOW THEY
23 CAN -- USUALLY IT'S SET AROUND ENROLLMENT ISSUES.
24 BUT WHEN YOU GET PATIENTS INVOLVED IN SOLVING
25 ENROLLMENT ISSUES IN CLINICAL TRIALS, YOUR CLINICAL

BARRISTERS' REPORTING SERVICE

1 TRIALS ENROLL FASTER. THERE'S THIS THING CALLED
2 PATIENT-CENTRIC ENROLLMENT. IF YOU HAVE A
3 PATIENT-CENTRIC ENROLLMENT, YOUR CLINICAL TRIALS
4 JUST ENROLL FASTER. AND SO ACTUALLY I'M SAD I
5 DIDN'T TALK ABOUT IT IN THE ENROLLMENT NUMBERS
6 BECAUSE I THINK IT PLAYED A SIGNIFICANT PART IN
7 THAT.

8 CHAIRPERSON YEE: GREAT. THANK YOU.
9 OTHER COMMENTS, MEMBERS?

10 DR. SADANA: THAT WAS AN EXCELLENT
11 PRESENTATION. THANK YOU. AND I WILL SAY THIS IS
12 THE FIRST TIME WE GOT A REAL PICTURE OF WHAT'S GOING
13 ON OVER THESE YEARS, THE LAST DECADE. IT WAS KIND
14 OF MORE OF AN EMOTIONAL THING WHICH IS GOING ON.

15 ONE QUESTION. I DON'T MEAN TO SOUND
16 NEGATIVE, BUT LET'S SAY THIS WAS A PRIVATE INDUSTRY.
17 WOULD STILL CIRM BE AROUND WITH THIS MUCH MONEY?

18 DR. MILLS: NO. I THINK THAT'S KIND OF
19 THE POINT OF CIRM WAS TO DO SOMETHING THAT YOU
20 COULDN'T JUSTIFY THROUGH THE FREE MARKET BECAUSE THE
21 TIME AND THE RISK PROFILE. IF YOU JUST DO THE NPD
22 ON THAT EARLY MONEY WE INVESTED, IT'S JUST NOT
23 THERE. I DIDN'T COME UP WITH THIS. JIM COLLINS
24 ACTUALLY CAME UP WITH THIS. GIANT FLYWHEEL ANALOGY
25 WHERE IT'S A REALLY HEAVY DISK AND IT TAKES A LONG

BARRISTERS' REPORTING SERVICE

1 TIME TO GET STARTED AND YOU MOVE IT IMPERCEPTIBLY.
2 ONCE THAT THING GETS TURNING, IT'S ALMOST IMPOSSIBLE
3 TO STOP. GIANT HEAVY FLYWHEEL HAS A LOT OF MOMENTUM
4 ASSOCIATED WITH IT. THIS FLYWHEEL IS STARTING TO
5 CRANK UP NOW.

6 LAST YEAR WE HAD TEN TRIALS. NOW WE HAVE
7 22. THAT NUMBER IS GROWING SO FAST, IT'S HARD TO
8 KEEP -- WE PUT FIVE TRIALS IN IN LIKE THE LAST
9 QUARTER. THAT MANY TRIALS -- BASICALLY THE WAY WE
10 DESIGNED IT WAS WE KNOW, WE KNOW WE'RE GOING TO HAVE
11 THERAPEUTIC SUCCESS, ACTUALLY GET TO THE MARKET,
12 BECAUSE WE DESIGNED THE SYSTEM TO HAVE THOSE KINDS
13 OF NUMBERS IN THERE, KNOWING WE'RE GOING TO HAVE
14 FALLOUT, BUT WE'RE GOING TO PUT 65 THINGS IN WITH
15 OUR TRIAL SPREAD. WE KNOW WE'RE GOING TO GET
16 SOMETHING LIKE FOUR TO SEVEN PRODUCTS ACTUALLY ON
17 THE MARKET. IT'S DIFFICULT TO SEE YET.

18 I'M NOT A -- I DON'T LIKE THE EMOTIONAL
19 COMPONENTS OF IT. I'M AN EMOTIONAL PERSON. I DON'T
20 LIKE THE -- I'M MORE LIKE LET'S LET THE SCOREBOARD
21 DO THE TALKING. AND SO ALL I CAN REALLY SAY IS,
22 WITHOUT OVERHYPING THIS, IS JUST TO STAND BY.
23 WHAT'S COMING IS GOOD.

24 DR. SADANA: THANK YOU.

25 CHAIRPERSON YEE: THANK YOU.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN THOMAS: THANK YOU, MADAM
2 CONTROLLER. SO I JUST WOULD LIKE TO ADD TO THAT.
3 THE WHOLE IDEA OF PROP 71 WAS THAT THE INDUSTRY AND
4 THE THEN FLEDGLING CELLULAR THERAPY BUSINESS WAS NOT
5 REALLY GOING TO GET INTO R & D AND WHAT IT TOOK TO
6 GET TO PROOF OF CONCEPT AT THE END OF PHASE II
7 CLINICAL TRIALS. AND SO CIRM WAS CREATED. WE CALL
8 THAT THE VALLEY OF DEATH, WHICH SOUNDS LIKE A
9 DISEASE TERM. IT'S REALLY AN ECONOMIC TERM. THEY
10 JUST WOULD NOT STEP IN. AND CIRM WAS CREATED TO
11 FUND ALL THE BASIC RESEARCH THROUGH THE END OF THE
12 PHASE II CLINICAL TRIALS SO THAT YOU WOULD GET TO
13 PROOF OF CONCEPT AND WOULD ULTIMATELY GET INDUSTRY
14 INTERESTED TO PICK IT UP.

15 SO IT WAS NOT CONTEMPLATED THAT THE
16 FUNDING THAT CIRM WAS PUTTING IN WAS GOING TO
17 IMMEDIATELY HAVE ANY ECONOMIC RETURN. THE WHOLE
18 POINT WAS TO DRIVE INNOVATION AND DRIVE CELLULAR
19 THERAPY FROM ITS FLEDGLING FORM INTO SOMETHING THAT
20 WOULD TRULY BECOME OF INTEREST TO INDUSTRY. AND
21 THAT'S WHAT RANDY IS TALKING ABOUT IS WE'RE READILY
22 HEADING TOWARDS THAT POINT AND FIRMLY BELIEVE THAT
23 WHEN HISTORY LOOKS BACK, THAT CIRM WILL HAVE DONE
24 EXACTLY WHAT IT WAS SET UP TO DO TO MAKE THAT
25 HAPPEN.

BARRISTERS' REPORTING SERVICE

1 CHAIRPERSON YEE: OKAY. THANK YOU VERY
2 MUCH, DR. MILLS.

3 DR. MILLS: THANK YOU.

4 CHAIRPERSON YEE: WONDERFUL PRESENTATION.
5 THANK YOU.

6 WHY DON'T WE MOVE ON TO THE NEXT ITEM
7 THEN, WHICH IS THE CIRM FINANCIAL UPDATE. AND WE'LL
8 HEAR FROM CHILA SILVA-MARTIN, WHO IS THE FINANCE
9 DIRECTOR.

10 MS. SILVA-MARTIN: GOOD MORNING,
11 CONTROLLER YEE AND MEMBERS OF THE COMMITTEE. IT'S
12 ALWAYS VERY DIFFICULT TO FOLLOW BEHIND DR. MILLS
13 BECAUSE HE DOES DO SUCH A FABULOUS PRESENTATION.

14 THIS MORNING I WILL BE PROVIDING YOU A
15 FINANCIAL REPORT. THE REPORT WILL COVER THE '15-'16
16 BUDGET. WE'LL LOOK AT WHAT WAS APPROVED FOR THAT
17 FISCAL YEAR, WHERE WE EXPECT OUR FINAL NUMBERS TO
18 END, AND SOME MAJOR DRIVERS THAT IMPACTED THOSE
19 FINAL NUMBERS, AND THEN WE'LL MOVE ON AND LOOK AT
20 THE '16-'17 BUDGET. WE'LL LOOK AT SOME MAJOR
21 DRIVERS BEHIND THAT BUDGET AS WELL AS SOME POTENTIAL
22 RISKS THAT WE MAY FACE IN MEETING THE FULL BUDGET.

23 BEFORE I ACTUALLY GO INTO THE '15-'16
24 NUMBERS, I'D LIKE TO EXPLAIN WHY THE INFORMATION I'M
25 GOING TO PROVIDE YOU FOR '15-'16 IS PROJECTED

BARRISTERS' REPORTING SERVICE

1 INSTEAD OF ACTUALS. AS YOU KNOW, THE STATE FISCAL
2 YEAR IS FROM JULY 1 THROUGH JUNE 30TH. SO BY NOW
3 NORMALLY WE WOULD HAVE HAD OUR AUDIT COMPLETED.
4 BUT, AS YOU KNOW, THE STATE OF CALIFORNIA
5 IMPLEMENTED A NEW FINANCIAL MANAGEMENT SYSTEM CALLED
6 FI\$CAL. IT IMPLEMENTED -- THE SYSTEM IS BEING
7 INTRODUCED IN WAVES THROUGHOUT THE STATE OF
8 CALIFORNIA. SO EVERY YEAR THEY'RE ADDING NEW
9 DEPARTMENTS AND THEY'RE ADDING NEW FUNCTIONALITY.

10 WE CONTRACT WITH THE DEPARTMENT OF GENERAL
11 SERVICES FOR OUR ACCOUNTING OFFICE. AND SO AS A
12 RESULT OF THAT, WE WERE REQUIRED TO COME ONTO FI\$CAL
13 AS A WAVE 2 DEPARTMENT DURING THE '15-'16 FISCAL
14 YEAR.

15 UNFORTUNATELY, BECAUSE WE ARE A BOND
16 AGENCY, NOT ALL OF THE FUNCTIONALITY THAT WE REQUIRE
17 FOR OUR FINANCIAL STATEMENTS IS YET AVAILABLE IN THE
18 SYSTEM. IT ACTUALLY ISN'T GOING TO GO LIVE UNTIL
19 THE CONTROLLER'S GOES LIVE IN 2017. SO FOR THE
20 '15-'16 FISCAL YEAR, WHAT REALLY HAPPENED, THEN, IS
21 THAT ALL OF OUR TRANSACTIONS HAD TO BE PERFORMED
22 MANUALLY. CLAIM SCHEDULES HAD TO BE -- PAPER CLAIMS
23 SCHEDULES HAD TO BE SUBMITTED TO THE CONTROLLER'S,
24 THEY PAID THEM OUTSIDE OF THE FI\$CAL SYSTEM, AND
25 THEN THAT REQUIRED GENERAL SERVICES TO THEN GO BACK

BARRISTERS' REPORTING SERVICE

1 IN AND INPUT THEM MANUALLY INTO FISCAL. SO AS YOU
2 CAN SEE, A LOT OF DUPLICATION OF EFFORT. AND, OF
3 COURSE, THERE WAS ALWAYS THE CHALLENGE OF BRINGING
4 OUR BEGINNING NUMBERS FORWARD.

5 SO FOR ALL OF THOSE REASONS, IT HAS TAKEN
6 SOME TIME TO GET OUR BOOKS CLOSED. WE DO KNOW THAT
7 DEPARTMENT OF GENERAL SERVICES HAS NOW POSTED
8 EXPENDITURES THROUGH DECEMBER. SO THEY ARE WORKING
9 ON ACCRUALS, AND WE EXPECT THAT THEY WILL HAVE THEIR
10 FINANCIAL STATEMENTS HOPEFULLY COMPLETED WITHIN THE
11 NEXT TWO TO THREE WEEKS. SO THAT IS WHY YOU HAVE
12 PROJECTED NUMBERS, BUT THE NUMBERS ARE COMING OUT OF
13 THE FISCAL SYSTEM AS WELL AS SOME INTERNAL RECORDS
14 THAT WE HAVE.

15 SO NOW LOOKING AT THOSE NUMBERS. SO THIS
16 CHART HERE PROVIDES YOU WITH A SNAPSHOT OF OUR
17 '15-'16 BUDGET AT THE CATEGORICAL LEVEL. SO THE
18 FIRST COLUMN REPRESENTS THE BUDGET THAT THE BOARD
19 APPROVED FOR CIRM DURING THE '15-'16 FISCAL YEAR,
20 AND THAT WAS AT 18.7 MILLION. THE SECOND COLUMN
21 REPRESENTS WHERE WE EXPECT TO END THE FISCAL YEAR,
22 AND THAT'S AT 17.2 MILLION. AND SO THE DIFFERENCE,
23 THE VARIANCE, THE UNDERRUNS AND OVERRUNS, IS
24 REPRESENTED IN THE THIRD COLUMN. SO WE EXPECT OUR
25 BUDGET TO COME IN AT ABOUT \$1.5 MILLION LESS THAN

BARRISTERS' REPORTING SERVICE

1 WHAT WE WERE BUDGETED, OR ABOUT 8 PERCENT.

2 SO IF YOU LOOK AT THE THIRD COLUMN, YOU
3 CAN SEE THAT THERE'S A FEW AREAS WHERE WE HAVE SOME
4 FAIRLY SIGNIFICANT EITHER UNDERRUNS OR OVERRUNS.
5 THERE ARE TWO AREAS WHERE WE HAVE UNDERRUNS, A LARGE
6 AMOUNT OF UNDERRUNS, AND THAT'S IN OUR EMPLOYEE
7 EXPENSES AND REVIEWS, MEETINGS CATEGORIES. AND THEN
8 WE DO HAVE ONE AREA WHERE WE HAD AN OVERRUN. SO I'D
9 JUST LIKE TO TALK BRIEFLY ABOUT THOSE.

10 SO FIRST LOOKING AT THE UNDERRUNS. SO OUR
11 EMPLOYEE EXPENSES ARE EXPECTED TO COME IN ABOUT 1.2
12 MILLION UNDER WHAT WAS BUDGETED. SO WHY DID THIS
13 HAPPEN? SO AS YOU KNOW, DR. MILLS HAS TALKED A LOT
14 ABOUT THE REORGANIZATION AND STRATEGIC PLANNING, AND
15 SO THAT OCCURRED DURING THE '14-'15 FISCAL YEAR AS
16 WELL AS THE '15-'16. SO AT THE BEGINNING OF THE
17 '15-'16 FISCAL YEAR, WE HAD SEVERAL POSITIONS THAT
18 WERE VACANT; BUT WE WERE GOING THROUGH THE FINAL
19 REORGANIZATION PROCESS, AND THEN WE IMPLEMENTED THE
20 STRATEGIC PLANNING PROCESS. AND SO WE MADE A
21 DECISION THAT WE WOULD KEEP THOSE POSITIONS VACANT
22 UNTIL WE HAD A BETTER UNDERSTANDING OF WHERE WE WERE
23 GOING. AND THEN ONCE THAT WAS ALL DONE, WE WOULD
24 MOVE FORWARD AND FILL THOSE POSITIONS. SO FOR A
25 MAJORITY OF THAT FISCAL YEAR POSITIONS WERE LEFT

BARRISTERS' REPORTING SERVICE

1 VACANT. WE DID START FILLING THEM AT THE END OF THE
2 FISCAL YEAR AFTER WE GOT OUR STRATEGIC PLANNING
3 PROCESS APPROVED.

4 THE OTHER AREA WHERE WE SAW A SIGNIFICANT
5 UNDERRUN WAS IN REVIEWS, MEETINGS, AND WORKSHOPS.
6 AND THAT REALLY OCCURRED FOR TWO REASONS. SO WE
7 IMPLEMENTED CIRM 2.0 IN OUR DISCOVERY AND
8 TRANSLATIONAL PROGRAMS TOWARD THE END OF THE
9 '14-'15, '15-'16 FISCAL YEAR. AND SO WE HAD PLANNED
10 IN THE BUDGET, THE '15 BUDGET INCLUDED FOUR REVIEWS
11 FOR DISCOVERY AND TRANSLATIONAL. WE ACTUALLY ONLY
12 HELD THREE. SO WE HAD SAVINGS FROM THAT.

13 WE ALSO DID A LOT OF RESTRUCTURING, AS DR.
14 MILLS HAS TALKED TO YOU ABOUT, AND MADE A LOT OF
15 EFFICIENCIES. SO ONE AREA WHERE WE HAD SOME CHANGES
16 IN OUR MEETINGS WAS, FOR EXAMPLE, IN OUR ICOC
17 MEETINGS. PREVIOUSLY UNDER CIRM 1.0, WE HELD
18 ANYWHERE FROM SIX TO SEVEN IN-PERSON ICOC MEETINGS.
19 WE NOW ARE HOLDING MONTHLY MEETINGS FOR THE ICOC.
20 THERE ARE NOW FOUR IN-PERSON AND THEN THREE
21 TELEPHONIC, SO THAT'S ACTUALLY INCREASED THE NUMBER
22 OF MEETINGS WE HAD, BUT WE'RE HAVING LOWER COST
23 BECAUSE WE'RE NO LONGER HAVING THEM IN PERSON.

24 SIMILARLY, FOR SOME OF OUR OTHER PROGRAMS,
25 THE LIKE AND THE CAPS AND OUR ALPHA CLINICS,

BARRISTERS' REPORTING SERVICE

1 PREVIOUSLY WE HELD THOSE MEETINGS AT PRIVATE VENUES,
2 AND SO WE WERE REQUIRED TO PAY FOR THOSE VENUES.
3 WITH THE RESTRUCTURING, WE BROUGHT THOSE MEETINGS TO
4 OUR GRANTEE LOCATIONS, AND WE ARE HAVING THEM MORE
5 OFTEN, BUT WE'RE SEEING LOWER COST.

6 SO THERE IS ONE AREA WHERE WE DID SEE AN
7 OVERRUN, AND THAT'S IN OUR FACILITIES. SO AS YOU
8 MAY RECALL, FOR THE FIRST 15 -- EXCUSE ME. FOR THE
9 FIRST 11 YEARS OF CIRM'S EXISTENCE, WE HAD A REALLY
10 UNIQUE BENEFIT. WE DIDN'T PAY FOR RENT. WE WERE IN
11 A BUILDING WHERE WE WERE PROVIDED RENT, ALL THE
12 OPERATIONAL EXPENSES, INCLUDING PARKING FOR OUR
13 EMPLOYEES FOR FREE. THAT EXPIRED IN OCTOBER OF
14 2015. SO WE WERE REQUIRED TO GO OUT AND LOOK FOR
15 NEW SPACE. SO WE CONDUCTED A VERY EXTENSIVE SITE
16 SEARCH. WE LOOKED IN SAN FRANCISCO, IN THE
17 PENINSULA, AND THE EAST BAY. AND WE ENDED UP
18 SELECTING OAKLAND AS OUR HEADQUARTERS.

19 THE LOCATION THAT WE SELECTED WAS IN A
20 SHELL CONDITION, AND WE WERE REQUIRED TO BUILD IT
21 OUT. SO WE REALLY HAD TWO OPTIONS FOR THAT
22 BUILDOUT. WE COULD FINANCE IT THROUGHOUT THE TERM
23 OF THE LEASE, INCLUDED IN THE RENT, BUT THAT WOULD
24 HAVE REQUIRED FINANCING THAT THE OWNERSHIP WOULD
25 HAVE HAD TO PASS ON TO US. OUR OTHER OPTION WAS TO

BARRISTERS' REPORTING SERVICE

1 JUST PAY THE MONEY UP FRONT, AND THAT'S WHAT WE
2 ELECTED TO DO BECAUSE IT WAS A SAVINGS TO THE STATE
3 OF CALIFORNIA.

4 SO ALTHOUGH WE HAD TO PAY FOR THE COST OF
5 RELOCATING THE OFFICE AND THESE BUILDOUT COSTS,
6 THESE ONE-TIME COSTS, IT WAS STILL BETTER TO MOVE TO
7 OAKLAND BECAUSE, HAD WE STAYED AT OUR LOCATION IN
8 SAN FRANCISCO OVER THE FIRM TERM OF THE OAKLAND
9 LEASE, IT WOULD HAVE COST US ABOUT \$3 MILLION MORE
10 TO STAY IN SAN FRANCISCO.

11 SO THAT'S JUST A VERY QUICK LOOK AT THE
12 '15-'16 BUDGET, AND I'D LIKE TO MOVE OVER TO THE
13 '16-'17 BUDGET.

14 SO NOW THIS CHART PROVIDES YOU A SNAPSHOT
15 OF OUR '16-'17 BUDGET. SO AS YOU CAN SEE BY THE
16 THIRD COLUMN, WE ARE ALLOCATED FOR THIS YEAR \$18.9
17 MILLION. IF YOU COMPARE THAT TO WHAT WE WERE
18 ALLOCATED FOR '15-'16, WHICH IS THE FIRST COLUMN,
19 IT'S \$18.7 MILLION. SO WE'RE JUST LOOKING AT AN
20 INCREASE OF \$200,000 FOR THIS NEW FISCAL YEAR.

21 NOW, COMPARING IT TO WHERE WE EXPECT THE
22 '15-'16 YEAR TO END, WHICH IS \$17.2 MILLION AS
23 REFLECTED IN THE SECOND COLUMN, WE'RE LOOKING AT
24 ABOUT A \$1.7 MILLION DIFFERENCE. SO WHY ARE WE
25 SEEING THIS VARIANCE OF \$1.7 MILLION BETWEEN WHERE

BARRISTERS' REPORTING SERVICE

1 WE LANDED IN '15-'16 AND WHERE WE EXPECT TO BE THIS
2 YEAR? I'D LIKE TO JUST TALK ABOUT THAT BRIEFLY.

3 SO LOOKING AT THIS CHART, YOU CAN SEE THAT
4 THERE ARE A COUPLE OF AREAS WHERE WE'RE ANTICIPATING
5 INCREASES OVERALL IN OUR EMPLOYEE EXPENSES AND OUR
6 REVIEWS, MEETINGS, AND WORKSHOPS. AND THEN WE DO
7 ANTICIPATE THAT THE COST WILL GO DOWN FOR OUR
8 FACILITIES. SO I'D LIKE TO JUST TALK BRIEFLY ABOUT
9 EACH OF THOSE.

10 SO WE ARE ANTICIPATING INCREASED COSTS,
11 AND THERE'S REALLY TWO REASONS BEHIND THAT. I
12 TALKED ABOUT ONE OF THEM EARLIER. SO WE HAVE
13 HAD -- WE HAD SEVERAL VACANCIES DURING THE '15-'16
14 FISCAL YEAR. ONCE WE FINISHED THE STRATEGIC
15 PLANNING PROCESS, WE STARTED FILLING SOME OF THOSE
16 POSITIONS. WE WERE SUCCESSFUL IN FILLING SOME, AND
17 WE'RE CURRENTLY ACTIVELY RECRUITING FOR OTHERS. SO
18 WE ANTICIPATE THAT OVERALL THOSE COSTS ARE GOING TO
19 GO UP BECAUSE POSITIONS HAVE BEEN FILLED.

20 ANOTHER FACTOR THAT'S IMPACTING THE AMOUNT
21 OF MONEY THAT WE ANTICIPATE WE'LL SPEND ARE WHAT WE
22 CALL STATE-IMPOSED CONTRIBUTIONS THAT AS EMPLOYERS
23 WE'RE REQUIRED TO PAY ON BEHALF OF OUT OF EMPLOYEES.
24 AS A STATE AGENCY, WE DO FUND RETIREMENT AND HEALTH
25 BENEFITS FOR OUR EMPLOYEES. BASED ON INFORMATION

BARRISTERS' REPORTING SERVICE

1 THAT WE RECEIVED WHEN WE WERE BUILDING THE BUDGET
2 FROM THE VARIOUS CONTROL AGENCIES LIKE CALPERS AND
3 CALHR, WE WERE ADVISED THAT THOSE COSTS WERE GOING
4 TO BE GOING UP. AND SO WE BUILT A 7-PERCENT
5 INCREASE IN THE BUDGET TO COVER THOSE COSTS.

6 WE ALSO EXPECT THAT OUR REVIEW ACTIVITY
7 COSTS WILL GO UP. SO FOR THE '16-'17 FISCAL YEAR,
8 AS DR. MILLS INDICATED, WE ARE SCHEDULED TO HOLD 20
9 REVIEWS. THAT'S IN COMPARISON TO FOUR TO SEVEN
10 REVIEWS THAT WE HELD UNDER CIRM 1.0. SO THAT'S LIKE
11 3 TO 400-PERCENT INCREASE. WE ARE EXPECTING TO SEE
12 AN INCREASE OF JUST ONLY \$400,000 FOR HOLDING 400
13 PERCENT MORE MEETINGS, SO THAT REALLY SPEAKS TO ALL
14 THE EFFICIENCIES THAT HAVE BEEN IMPLEMENTED THROUGH
15 CIRM 2.0.

16 THERE IS ONE AREA WHERE WE DO ANTICIPATE
17 THAT THE COSTS WILL GO DOWN, AND THAT'S IN THE
18 FACILITIES. SO FOR THE FIRST TIME IN OUR HISTORY WE
19 HAVE AN ANNUALIZED COST IN THE '16-'17 FISCAL YEAR
20 OF \$710,000. THAT'S DOWN ABOUT 787, \$789,000 FROM
21 WHAT WE SPENT LAST YEAR, BUT THAT AMOUNT REALLY
22 REPRESENTED THOSE ONE-TIME COSTS FOR THE BUILDOUT
23 AND THE RELOCATION THAT WE WILL NOT INCUR THIS YEAR.

24 SO DR. MILLS TALKED ABOUT RISKS WITH OUR
25 STRATEGIC PLAN, AND I'M GOING TO TALK ABOUT RISKS

BARRISTERS' REPORTING SERVICE

1 AND REALLY MEETING THE FULL BUDGET FOR THE '16-'17
2 FISCAL YEAR BECAUSE WE DO FACE SOME OF THOSE. SO
3 ONE RISK IS IN OUR APPLICATION VOLUME. WE ARE
4 INCREASING THE NUMBER OF REVIEWS THAT WE WILL HOLD
5 THIS FISCAL YEAR, BUT WE DON'T CONTROL THE NUMBER OF
6 APPLICATIONS THAT COME IN. SO WE HAVE BUDGET BASED
7 ON OUR HISTORICAL INFORMATION, BUT IT'S POSSIBLE
8 THAT WE WILL RECEIVE MORE APPLICATIONS THAN WE
9 BUDGETED FOR, AND WE MAY SEE AN OVERRUN IN THIS
10 AREA.

11 WE TALKED A LOT ABOUT THE VACANT
12 POSITIONS. WE STILL CONTINUE TO HAVE SOME VACANT
13 POSITIONS. WHEN WE FIRST ESTABLISHED THIS BUDGET,
14 WE DID IT LARGELY BASED ON THE CIRM 1.0 BECAUSE WE
15 HAD A LOT OF EXPERIENCE THERE. WE DON'T HAVE A LOT
16 OF EXPERIENCE WITH WHAT WE'LL NEED IN CIRM 2.0. WE
17 TRIED TO BE CONSERVATIVE IN OUR ESTIMATE, BUT WE'VE
18 IMPLEMENTED MANY, MANY EFFICIENCIES THROUGHOUT THE
19 ORGANIZATION. SO AS WE GAIN MORE EXPERIENCE, WE MAY
20 DECIDE THAT WE WILL NOT FILL THE REMAINDER OF OUR
21 VACANCIES. AND IF THAT OCCURS, WE MAY CONTINUE TO
22 HAVE AN UNDERRUN IN THIS AREA.

23 ANOTHER AREA THAT WE CAN'T REALLY PREDICT
24 COMPLETELY OR CONTROL ARE THOSE STATE-IMPOSED
25 CONTRIBUTIONS. SO WHEN WE BUILT THE BUDGET, WE

BARRISTERS' REPORTING SERVICE

1 BUILT IT BASED ON WHAT INFORMATION WE HAD AT THE
2 TIME. WE KNEW THAT RETIREMENT WAS GOING UP AND WE
3 KNEW THAT HEALTH BENEFITS WERE BEING AFFECTED. BUT
4 THE STATE OF CALIFORNIA IS CURRENTLY IN NEGOTIATIONS
5 WITH A NUMBER OF UNIONS, AND WE ARE ALREADY STARTING
6 TO SEE SOME OF THE RESULTS OF THOSE, AND WE ARE
7 SEEING SOME INCREASED COSTS. AND SO WE ANTICIPATE
8 THAT WHEN ALL OF THAT IS SAID AND DONE AND ALL THE
9 NEGOTIATIONS ARE COMPLETE, THAT WE WILL PROBABLY SEE
10 SOME INCREASES IN THAT AREA. SO GIVEN THAT, IT'S
11 VERY POSSIBLE THAT WE WILL SEE INCREASES THERE THAT
12 WE DID NOT ANTICIPATE.

13 AND THAT REALLY IS THE BUDGET IN A
14 NUTSHELL. I'M HAPPY TO ANSWER ANY QUESTIONS ANY OF
15 YOU HAVE. THIS HAS BEEN A CHALLENGING YEAR FOR US
16 BECAUSE WE DON'T HAVE OUR BOOKS CLOSED YET, BUT
17 WE'RE CONFIDENT THAT WE WILL OVERCOME ALL OF THIS,
18 AND AT SOME POINT WE WILL BE ABLE TO USE FISCAL AS
19 IT WAS INTENDED. AND WE'RE LOOKING FORWARD TO THAT.

20 CHAIRPERSON YEE: GREAT. THANK YOU,
21 CHILA. JUST WOW. FOR THE SAKE OF DR. QUICK AND
22 DR. SEDANA, THE FISCAL PROJECT, WHICH IS OUR
23 STATEWIDE, ESSENTIALLY BUILDING A SYSTEM FOR OUR
24 STATEWIDE ACCOUNTING, HAS BEEN CHALLENGING. AND I
25 WILL SAY THAT WITH RESPECT TO CIRM, WE'RE FURTHER

BARRISTERS' REPORTING SERVICE

1 THAN EVEN SOME OTHER STATE DEPARTMENTS. LOTS OF
2 CHALLENGES. AND CERTAINLY AS ONE OF THE CONTROL
3 AGENCIES INVOLVED, THE STATE CONTROLLER'S OFFICE, I
4 JUST WANT TO SAY THANK YOU FOR CONTINUING TO HANG IN
5 THERE WORKING WITH GENERAL SERVICES. I'M ACTUALLY
6 HAPPY THAT THE TIME FRAME IS WITHIN REACH IN TERMS
7 OF CLOSING OUT. SO THANK YOU FOR THAT.

8 A QUESTION WITH RESPECT TO THE UNFILLED
9 POSITIONS. GIVE US A FLAVOR OF THE TYPES OF
10 POSITIONS. IS THIS GOING TO AFFECT ANYTHING IN
11 TERMS OF THE -- ANYTHING MISSION CRITICAL?

12 DR. MILLS: SO THIS IS, AS I ALLUDED TO IN
13 MY PRESENTATION, THIS IS THE CURVE BALL THAT I
14 CONTINUE TO THROW CHILA. THE UNFILLED POSITIONS
15 AREN'T THAT WE CAN'T FILL THEM. IT'S THAT
16 PRODUCTIVITY AND EFFICIENCY ARE GOING UP SO QUICKLY,
17 WE'RE REALIZING THAT WE MAY JUST NOT NEED TO FILL
18 THEM. SO ANYTHING MISSION CRITICAL WE HAD AND WE
19 GET. WE MADE TWO HIRES WITHIN THE LAST FEW WEEKS.
20 SO IF WE NEED PEOPLE, WE'RE STILL GETTING GREAT
21 QUALITY PEOPLE. BUT WHAT WE WON'T DO IS WE WON'T
22 OVERSTAFF BECAUSE I DON'T WANT TO HAVE TO LET
23 SOMEBODY GO, I DON'T WANT THERE TO BE PEOPLE SITTING
24 AROUND WITHOUT ANY WORK TO DO. SO WE'RE REALLY JUST
25 TRYING TO GET OUR HAND. I KNOW IT LOOKS LIKE WE

BARRISTERS' REPORTING SERVICE

1 CAN'T BUDGET, BUT IT'S JUST WE'RE IN A SYSTEM THAT'S
2 CHANGING SO FAST, THE PRODUCTIVITY IS CHANGING SO
3 FAST, IT'S VERY DIFFICULT FOR US TO FIGURE OUT. SO
4 IF WE NEED THEM, WE PUT THE SLOTS THERE. BUT WE
5 TALKED ABOUT EARLIER, THERE IS ALMOST NO CHANCE THAT
6 WE'RE ACTUALLY GOING TO COME IN AT BUDGET ON
7 EMPLOYEE COSTS. THEY WILL BE LOW AGAIN. AND THEN
8 EVENTUALLY WE'LL PROBABLY HAVE A HANDLE ON THE
9 SYSTEM AND CAN ACTUALLY THEN NEXT YEAR FORECAST
10 CORRECTLY.

11 CHAIRPERSON YEE: OKAY. THANK YOU.
12 QUESTIONS, MEMBERS? THANK YOU VERY MUCH.

13 MS. SILVA-MARTIN: THANK YOU.

14 CHAIRPERSON YEE: OKAY. OUR NEXT ITEM,
15 CLINICAL PORTFOLIO REVIEW. DR. MILLS.

16 DR. MILLS: I'M BACK. OKAY. THOUGHT IT
17 WOULD BE FUN JUST TO TAKE YOU THROUGH WHAT WE'VE
18 DONE AT CIRM WITH REGARDS TO CLINICAL. WE HAVE
19 ABOUT 300 PROJECTS ALL TOLD AT CIRM IN ALL OF THOSE
20 DIFFERENT AREAS THAT WE DO. BUT THE ONES THAT
21 PEOPLE GENERALLY LIKE TO TALK ABOUT AND FOCUS ON ARE
22 THE ONES THAT DEAL WITH OUR CLINICAL PORTFOLIO
23 BECAUSE IT'S CLOSEST TO ACTUALLY ACHIEVING OUR
24 MISSION.

25 SO, AGAIN, OUR SEAMLESS PATHWAY,

BARRISTERS' REPORTING SERVICE

1 DISCOVERY, TRANSLATION, AND TO CLINICAL. I WILL
2 NOTE ABOUT THIS, ONE OF THE THINGS ABOUT THIS SYSTEM
3 THAT WE REALLY LIKE IS THAT WITHIN EACH OF THESE
4 GROUPS WE HAVE MULTIPLE PROGRAMS. BUT THOSE
5 PROGRAMS ARE NOW SET UP SUCH THAT THE PRODUCT OF ANY
6 ONE AWARD IS THE PREREQUISITE FOR THE NEXT. SO
7 THERE ARE NO GAPS FROM THE EARLIEST STAGE IDEA ALL
8 THE WAY THROUGH GETTING A TRIAL REGISTERED. BECAUSE
9 OF THE WAY THE TIME IS SET UP, AS SOON AS YOU'RE
10 READY TO GO AND TO MAKE THAT JUMP OR THAT
11 PROGRESSION EVENT, AS I SAID, WE'RE THERE FOR YOU.
12 SO WE LIKE THAT TIME, WE LIKE OUR GAP TIME TO BE
13 ZERO.

14 NOW, DIGGING IN A LITTLE BIT MORE BETWEEN
15 THOSE THREE DOWN TO THE CLINICAL PROGRAM, IT IS
16 OFFERED 12 TIMES A YEAR OR ESSENTIALLY ALWAYS OPEN.
17 WE JUST CLOSE CYCLES TO REVIEW THEM AT THE END OF
18 EACH MONTH. WE HAVE THREE DIFFERENT PROGRAMS IN
19 CLINICAL. ONE IS FOR WHAT WE CALL IND ENABLING.
20 THE IND IS INVESTIGATIONAL NEW DRUG. IT'S THE
21 CERTIFICATION YOU GET FROM THE FOOD AND DRUG
22 ADMINISTRATION THAT ALLOWS YOU TO PUT INTO A HUMAN A
23 DRUG THAT IS NOT APPROVED. AND SO IT'S WHAT'S
24 REQUIRED IN ORDER TO CONDUCT A CLINICAL TRIAL. SO
25 OUR FIRST AWARD IN CLINIC IS AN 18-MONTH AWARD THAT

BARRISTERS' REPORTING SERVICE

1 LET'S THE APPLICANT GET THE IND.

2 ONCE THEY HAVE AN IND, WE HAVE A PROGRAM
3 CALLED CLIN2. AND CLIN2 IS FOR ANY STAGE CLINICAL
4 TRIAL. SO PHASE I, II, OR III CLINICAL TRIAL. AND
5 THEN, LASTLY, WE HAVE WHAT WE CALL A CLIN3 AWARD.
6 AND THIS IS REALLY FOR ACCELERATING ACTIVITIES. AND
7 THIS IS AN INFREQUENTLY USED, BUT IT WOULD BE A
8 GREAT THING TO USE, SO THIS WOULD BE IF WE HAD A
9 PROGRAM THAT WAS GOING ALONG, LET'S SAY, IN CANCER
10 AND IT WAS A 15-PATIENT TRIAL, BUT THE DATA IS JUST
11 COMING BACK OVERWHELMINGLY GREAT. AND THE FDA SAYS
12 IF YOU PUT 20 PATIENTS INTO THAT TRIAL, THEN WE'LL
13 LET YOU REGISTER THAT DRUG, GET IT APPROVED. SO THE
14 ACCELERATING OR THE CLIN3 AWARD ALLOWS FOR THOSE
15 TYPES OF ACTIVITIES WHERE YOU CAN TAKE A PROGRAM AND
16 TURN IT INTO A REGISTRATION PROGRAM.

17 OKAY. SO OUR EVER EXPANDING THERAPEUTICS
18 PORTFOLIO, 32 INDIVIDUAL PRODUCTS OR PROJECTS THAT
19 ARE IN THAT PORTFOLIO. YOU CAN SEE THE DIFFERENT
20 DISEASES WE HAVE REPRESENTED. THAT IS NOW 22
21 CLINICAL TRIALS. WE'LL PROBABLY END THE YEAR AT
22 SOMETHING CLOSER TO 27 CLINICAL TRIALS. SO WE'VE
23 GOT A BUNCH MORE THAT ARE COMING IN. AND TEN THINGS
24 GETTING READY TO GO INTO THE CLINIC, PRE-IND OR THAT
25 CLIN1 PHASE.

BARRISTERS' REPORTING SERVICE

1 THESE ARE THE DIFFERENT PROGRAMS. I'LL
2 BREAK OUT JUST THE CLINICAL ONES FOR THE DIFFERENT
3 CONDITIONS. SO THIS IS FOR OUR NEURO AND
4 OPHTHALMOLOGIC CONDITIONS. SO WE HAVE SPINAL CORD
5 INJURY, THAT'S IN A PHASE I-II; RETINITIS
6 PIGMENTOSA, WHICH IS BEING DONE IN IRVINE UNDER
7 DR. KLASSEN. I'LL TALK A LITTLE BIT MORE ABOUT THAT
8 IN A SECOND. THAT'S IN A PHASE I-II TRIAL. WE ALSO
9 HAVE ONE FOR AGE-RELATED MACULAR DEGENERATION, BACK
10 OF THE EYE, JUST LIKE RETINITIS PIGMENTOSA ACTUALLY.
11 THAT'S IN A PHASE I TRIAL. LOU GEHRIG'S DISEASE
12 JUST GOT APPROVED. THIS IS A BIG ONE. ALS,
13 AMYOTROPHIC LATERAL SCLEROSIS, PROGRAM AT
14 CEDARS-SINAI JUST GOT APPROVED. WE'RE VERY EXCITED
15 ABOUT THAT. WE HAVE AN OBSERVATIONAL TRIAL IN
16 HUNTINGTON'S DISEASE. AND OUR PREVIOUS SPINAL CORD
17 INJURY TRIAL IS NOW CLOSED.

18 WE HAVE ANOTHER GROUP WE CALL ORGAN
19 SYSTEMS. SO THESE ARE THINGS THAT GENERALLY RELATE
20 TO AN ORGAN OR A MUSCULOSKELETAL PROGRAM. SO WE
21 ACTUALLY HAVE A PHASE III PIVOTAL TRIAL THAT'S GOING
22 ON RIGHT NOW THAT ACTUALLY REGENERATES A BLOOD
23 VESSEL THAT ALLOWS PEOPLE UNDERGOING HEMODIALYSIS TO
24 BE ABLE TO CONTINUE TAKING THAT HEMODIALYSIS. THAT
25 TRIAL IS ACTUALLY AHEAD OF SCHEDULE. I LOVE THAT

BARRISTERS' REPORTING SERVICE

1 WHEN THAT HAPPENS. AND WHEN THEY'RE DONE, THAT
2 PRODUCT WILL GO DIRECTLY TO FDA FOR REGISTRATION,
3 HAS THE POSSIBILITY OF BEING OUR FIRST APPROVED
4 THERAPY.

5 WE ALSO HAVE A PHASE II TRIAL IN
6 MYOCARDIAL INFARCTION. SO WE'RE USING STEM CELLS
7 FOR PATIENTS THAT HAVE HAD A RECENT HEART ATTACK TO
8 PREVENT THEM FROM PROGRESSING INTO HEART FAILURE.

9 ONE OF OUR MOST COMPELLING PROGRAMS IS IN
10 CHILDREN WITH DUCHENNE'S MUSCULAR DYSTROPHY WHERE
11 ACTUALLY THEY HAVE A FORM OF THAT DISEASE WHERE THEY
12 ALSO GO INTO HEART FAILURE, AND WE HAVE A PHASE II
13 PROGRAM TRYING TO PREVENT THEM FROM PROGRESSING TO
14 HEART FAILURE.

15 WE HAVE A PHASE I-II TRIAL IN TYPE 1
16 DIABETES. AND, LASTLY, JUST STARTED A PHASE I-II
17 TRIAL IN OSTEONECROSIS. THIS IS A DISEASE THAT CAN
18 HAPPEN, SOMETIMES SPONTANEOUSLY IT CAN HAPPEN,
19 SOMETIMES AN INJURY, MOSTLY HAPPENS WHEN PEOPLE HAVE
20 TAKEN HIGH DOSES OF STEROIDS. AND WHAT HAPPENS IS
21 USUALLY THEIR HIP WILL BECOME NECROTIC BECAUSE THERE
22 WON'T BE ANY BLOOD AND THE BONE DIES AND BECOMES
23 NECROTIC, AND THESE PEOPLE LOSE THE ABILITY TO WALK
24 BECAUSE OF IT. SO IT'S A VERY SIGNIFICANT DISEASE.

25 ONCOLOGY, FIVE CLINICAL PROGRAMS GOING ON

BARRISTERS' REPORTING SERVICE

1 IN ONCOLOGY, INCLUDING A PHASE III TRIAL IN
2 GLIOBLASTOMA. UCLA IS RUNNING A VERY PROMISING
3 PROGRAM IN SOLID TUMORS, SO THEY'RE TRYING TO
4 FIND -- EARLY PHASE I TRIAL IS TRYING TO FIND SOLID
5 TUMORS THAT ARE WORKING. CHRONIC LYMPHOCYTIC
6 LEUKEMIA IS BEING DONE AT UCSD. AND THEN WE HAVE
7 AML, ACUTE MYELOGENOUS LEUKEMIA, WHICH IS BEING DONE
8 AT STANFORD. AND HERE'S AN EXAMPLE OF A TRIAL THAT
9 WE RAN AND IT DIDN'T WORK AND IT CLOSED. SO THIS
10 WAS A \$20 MILLION AWARD TO JUST SORT OF GIVE YOU
11 REAL NUMBERS. THEY GOT \$3 MILLION INTO IT, THEY GOT
12 TO FUTILITY, THAT HAPPENS, IT'S THE WORLD WE LIVE
13 IN, THE PROGRAM CLOSED, AND THE 17 MILLION THAT WAS
14 REMAINING CAME BACK TO CIRM.

15 AND THEN THE LAST BUCKET IS OUR
16 HEMATOLOGY. WE HAVE A LOT GOING ON IN HEMATOLOGY,
17 AND SOME OF THE MOST IMPRESSIVE AND SUCCESSFUL WORK
18 THAT I'VE EVER SEEN. SO THERE IS -- WE HAVE A PHASE
19 I-II TRIAL IN SEVERE COMBINED IMMUNODEFICIENCY WHERE
20 WE'RE ACTUALLY MAKING BONE MARROW TRANSPLANT A
21 LITTLE BIT EASIER THERE. WE HAVE A PHASE I-II TRIAL
22 IN HIV/AIDS. WE ALSO HAVE TWO PHASE I TRIALS IN
23 HIV/AIDS. ONE OF THEM IS AIDS LYMPHOMA. WE HAVE A
24 PRODUCT I'LL TALK MORE ABOUT IN JUST A SECOND IN A
25 DISEASE CALLED CGD, CHRONIC GRANULOMATOUS DISEASE.

BARRISTERS' REPORTING SERVICE

1 THIS IS A CONDITION WHERE PEOPLE DON'T HAVE THE
2 ABILITY TO KILL BACTERIA THAT THEIR WHITE CELLS
3 AREN'T ABLE TO CAPTURE. HAPPENS IN CHILDREN.
4 HISTORICALLY THEY WOULD DIE BY AROUND THE AGE OF
5 TEN. NOW THEY CAN MAKE IT INTO THEIR TWENTIES, BUT
6 A BAD DISEASE. THAT SAME INVESTIGATOR THAT'S TAKING
7 THAT SAME APPROACH IS ALSO WORKING ON IT IN SICKLE
8 CELL, ALSO WORKING ON IT IN SEVERE COMBINED
9 IMMUNODEFICIENCY. SO THAT SAME APPROACH IS
10 POTENTIALLY TACKLING A NUMBER OF VERY SERIOUS AND
11 SIGNIFICANT DISEASES.

12 SO THAT'S VERY METHODICALLY WHERE WE ARE
13 AND THAT'S OUR CLINICAL PROGRAM. I'LL TALK A LITTLE
14 BIT ABOUT THE PEOPLE BEHIND OUR CLINICAL PROGRAM AND
15 TALK ABOUT SOME OF WHAT WE'RE SEEING.

16 SO THIS IS RETINITIS PIGMENTOSA. IF
17 YOU'RE NOT FAMILIAR WITH THE DISEASE, IT'S A DISEASE
18 OF YOUR RETINA WHERE YOU START LOSING THE CELLS IN
19 THE BACK OF THE EYE THAT HELP YOU SEE LIGHT. YOU
20 GET TUNNEL VISION, AND THAT TUNNEL VISION GETS
21 SMALLER AND SMALLER AND SMALLER UNTIL EVENTUALLY YOU
22 CAN'T SEE ANYMORE. SO WE'VE GIVEN THEM A \$17
23 MILLION AWARD, DR. KLASSEN, A \$17 MILLION AWARD TO
24 CONDUCT A PHASE I-II TRIAL WHERE THEY'RE ACTUALLY
25 INJECTING THESE NEURAL STEM CELLS INTO THE BACK OF

BARRISTERS' REPORTING SERVICE

1 THE EYE TO REPLACE THE CELLS THAT OTHERWISE HAVE
2 DIED.

3 SO THIS IS ROSIE. AND ROSIE IS A REAL
4 PERSON WHO PARTICIPATED IN THIS TRIAL. SHE ACTUALLY
5 CAME AND SPOKE BEFORE OUR BOARD. SHE GOT DIAGNOSED
6 WITH THIS DISEASE RIGHT AROUND THE TIME THAT SHE WAS
7 HAVING HER CHILDREN, HER TWINS. AND BY THE TIME THE
8 CHILDREN WERE BORN, SHE COULDN'T SEE ANYMORE. SHE
9 IS NOW ABLE TO READ WITH THIS. SO IT'S SMALL
10 NUMBERS, BUT FOR HER VERY SUCCESSFUL.

11 THIS IS CHRIS. CHRIS IS ACTUALLY HERE
12 FROM L.A. THIS IS OUR SPINAL CORD INJURY TRIAL
13 WHERE WE TAKE HUMAN EMBRYONIC STEM CELLS, WE INJECT
14 THEM DIRECTLY INTO PATIENTS THAT HAVE SPINAL CORD
15 INJURY IN AN ATTEMPT TO REGROW AND PRESERVE SPINAL
16 PATHWAYS IN THE AFFECTED AREA. AND SO SPECIFICALLY
17 THEY'RE LOOKING AT CERVICAL, SO IN THE NECK, SPINAL
18 CORD INJURIES, C5 TO C7, SO THAT'S THE NUMBER OF THE
19 VERTEBRAE YOU HAVE. YOU COUNT DOWN FROM THE ONE AT
20 THE TOP OF YOUR NECK, YOU CAN COUNT DOWN, FIVE TO
21 SEVEN IS ABOVE YOUR SHOULDERS. SO THESE PATIENTS
22 ARE REQUIRED TO HAVE NEUROLOGICALLY COMPLETE
23 CERVICAL INJURIES ABOVE THEIR SHOULDERS. SO THEY
24 CAN'T MOVE THEIR ARMS, THEY CAN'T MOVE THEIR LEGS,
25 THEY CAN'T FEED THEMSELVES, THEY CAN'T TEXT, THEY

BARRISTERS' REPORTING SERVICE

1 CAN'T DO ANY OF THAT STUFF.

2 AND THAT WAS THE WAY CHRIS WAS WHEN HE
3 ENTERED THE TRIAL, A MOTOR VEHICLE ACCIDENT, UNABLE
4 TO MOVE HIS ARMS. THEY RECENTLY DID A FEATURE ON
5 HIM. HE WAS SO ENTHUSIASTIC ABOUT THE IMPROVEMENT
6 THAT HE'S SEEN, HE'S HOLDING WEIGHTS ABOVE HIS HEAD.
7 IT'S PRETTY COOL. AGAIN, EARLY, SMALL TRIAL. WE
8 WANT TO SEE MORE OF THIS HAPPEN. WE WANT TO SEE
9 MORE OF IT HAPPEN WHEN WE'RE SURE, 100 PERCENT
10 CERTAIN, THAT IT'S THE STEM CELL THERAPY. BUT WHEN
11 YOU HAVE 20, 30, 40, 50 CLINICAL TRIALS, THIS KIND
12 OF STUFF DOES HAPPEN. WE'RE GOING TO SEE MORE AND
13 MORE PATIENTS THAT ARE GETTING BETTER THAT ARE
14 OBJECTIVELY RESPONDING TO THESE KIND OF THERAPIES.
15 SO A GOOD START AND A GREAT START FOR HIM.

16 IT WAS FUNNY. I MAY HAVE MENTIONED
17 TEXTING, BUT IT WAS A BIG DEAL TO HIM. HE DESCRIBED
18 HIS LIFE AFTER THE ACCIDENT AS JUST EXISTING. HE
19 COULDN'T DO ANYTHING. HE COULDN'T MOVE HIS ARMS.
20 HE WAS JUST EXISTING. AND, YOU KNOW, THE KIDS
21 TODAY, THEY LIKE TO TEXT. THAT'S HOW THEY
22 COMMUNICATE AND SOCIALIZE, AND SO THAT WAS FOR HIM,
23 IT WAS THE THING THAT, YEAH, I CAN LIFT WEIGHT OVER
24 MY HEAD, I CAN FEED MYSELF, BUT I CAN TALK TO
25 SOMEBODY THE WAY WE DO. SO I THOUGHT THAT WAS

BARRISTERS' REPORTING SERVICE

1 GREAT.

2 NOW, HERE'S A QUESTION ABOUT WHAT ONE
3 THING CAN I POINT TO. THIS, I CAN POINT TO THIS
4 ONE. THIS IS AMAZING. SO DON KOHN AT UCLA
5 DEVELOPED A PROGRAM WHERE HE CAN TAKE BONE MARROW
6 OUT OF PEOPLE AND HE CAN EDIT THE GENES OF THAT BONE
7 MARROW AND CORRECT FOR THE DEFECTIVE GENE AND PUT IT
8 BACK IN. THIS PARTICULAR CASE, CHRONIC
9 GRANULOMATOUS DISEASE, THIS IS A DISEASE WHERE YOUR
10 WHITE BLOOD CELLS CAN'T KILL BACTERIA. SO THEY CAN
11 EAT THE BACTERIA, BUT THEY DON'T MAKE A CHEMICAL
12 CALLED SUPEROXIDE. AND SUPEROXIDE IS WHAT
13 ULTIMATELY KILLS THESE BACTERIA INSIDE. SO THEY
14 HAVE ESSENTIALLY A VERY SERIOUS IMMUNE DEFICIENCY.
15 THEY GET LOTS OF INFECTIONS ALL THE TIME. THEY'RE
16 ALWAYS SICK. THEY'RE USUALLY, LIKE I SAID, BEFORE
17 THEY WOULD DIE BEFORE THE AGE OF TEN. NOW WITH
18 ANTIBIOTIC AND ANTI-FUNGAL PROPHYLAXIS, THEY CAN
19 MAKE IT INTO THEIR TWENTIES, BUT IT'S A BAD DISEASE.

20 SO THIS IS BRANDON. BRANDON, BEFORE HE
21 WAS TREATED HAD A PIECE OF HIS LIVER CUT OUT, HAD A
22 PIECE OF HIS LUNG CUT OUT, HAD PIECES OF HIS FACE
23 THAT HAD TO BE REMOVED, WAS CHRONICALLY SICK.
24 COULDN'T DO ANYTHING, CHRONICALLY SICK, 22-YEAR-OLD.
25 AND GOT TREATED IN DECEMBER OF 2015 WITH DON KOHN'S

BARRISTERS' REPORTING SERVICE

1 PROGRAM.
2 NOW, HE DOESN'T HAVE THE ABILITY
3 NATURALLY, GENETICALLY TO MAKE THIS PROTEIN THAT
4 CREATES SUPEROXIDE. HE CAN'T MAKE IT, DOESN'T HAVE
5 IT, DOESN'T EXIST IN HIM. THEY TOOK HIS BONE MARROW
6 OUT, THEY GENE EDITED IT, THEY PUT IT BACK IN, AND
7 HE IS MAKING THIS WORK. DIRECT, ABSOLUTELY CAN
8 MEASURE IT, THERE'S NO OTHER POSSIBLE EXPLANATION
9 FOR WHAT'S GOING ON, AND CLINICALLY HE'S DOING
10 GREAT. HE'S GOING BACK TO COLLEGE. HE WASN'T ABLE
11 TO GO TO COLLEGE. HE'S GOING BACK TO COLLEGE. HE'S
12 GOT A PART-TIME JOB WORKING ON A GOLF COURSE. AND
13 THERE'S NO OTHER EXPLANATION FOR HIS IMPROVEMENT.
14 SO THAT I CAN POINT TO YOU AS -- WE'RE DOING MORE.
15 WE'RE NOT ONE AND DONE. WE'LL CONTINUE TO OBVIOUSLY
16 DO THIS AND TRY TO GET THIS DRUG APPROVED AS QUICKLY
17 AS WE CAN. SMALL NUMBER DISEASE, VERY, VERY ORPHAN
18 CONDITION, WOULD NOT HAPPEN WITHOUT CIRM BECAUSE
19 THERE'S NO WAY A DRUG COMPANY WOULD SPEND THAT MUCH
20 MONEY TO DEVELOP A THERAPY WHEN THERE'S ONLY 20 NEW
21 PATIENTS A YEAR, BUT A CLEAR EXAMPLE OF CLINICAL
22 SUCCESS IN A VERY REAL PERSON AND IN A TREATMENT
23 MODALITY THAT CAN BE EXPANDED TO OTHER DISEASES. SO
24 THINK ABOUT THAT. THINK ABOUT YOU CAN PUT IT ON
25 TOP, NOW YOU GO AFTER, INSTEAD OF CGD, YOU GO AFTER

BARRISTERS' REPORTING SERVICE

1 SICKLE CELL DISEASE, WHICH WE HAVE A PHASE I-II
2 TRIAL IN SICKLE CELLS. HORRIBLE DISEASE THAT
3 AFFECTS LOTS AND LOTS OF PEOPLE. THESE THINGS WILL
4 SOON BE IN THE PAST AND WILL BE IN THE PAST BECAUSE
5 OF CIRM.

6 GO BACK IN REVERSE AND END WITH OUR
7 MISSION BECAUSE THAT'S WHAT THE PURPOSE OF THAT
8 CLINICAL PROGRAM IS ABOUT. IT'S ABOUT BRINGING IT
9 BACK TO PATIENTS AND ACCELERATING THOSE STEM CELL
10 TREATMENTS TO THOSE PATIENTS WITH UNMET MEDICAL
11 NEEDS. THAT'S WHAT I GOT.

12 CHAIRPERSON YEE: THANK YOU, DR. MILLS.
13 COMMENTS, MEMBERS? DR. SEDANA.

14 DR. SADANA: CONGRATULATE YOU ON THE
15 SUCCESS. THIS IS WONDERFUL. ONLY THING I DIDN'T
16 SEE WAS CF WHERE YOU DON'T HAVE ANY RESEARCH GOING
17 ON, CYSTIC FIBROSIS.

18 DR. MILLS: IN CF? I WISH I HAD THE REST.
19 SO OF THE 300 PROGRAMS, I DON'T KNOW ALL OF THE ONES
20 WE HAVE. WE DON'T HAVE ANYTHING IN THE CLINIC IN
21 CF, BUT I DO THINK WE HAVE SOMETHING, I THINK, IN
22 TRANSLATIONAL, BUT I WILL FIND OUT FOR YOU.

23 ONE OF THE THINGS THAT, AS AN AGENCY,
24 WE'RE SORT OF AT THE MERCY OF WHAT COMES TO US AND
25 WHAT APPLIES. AND I SAY SORT OF NOW BECAUSE WE'VE

BARRISTERS' REPORTING SERVICE

1 CHANGED THAT. WE USED TO BE COMPLETELY. WE WOULD
2 JUST LIKE, OH, HOPE STUFF COMES IN. WE NOW HAVE A
3 DIFFERENT FULL-CONTACT CIRM. WE GO HUNTING. SO
4 WHEN THERE ARE PROGRAMS THAT WE WANT, AND THEY'RE A
5 GREAT PROGRAM, WE GO OUT AND TRY TO GET THEM AND
6 BRING THEM IN AND HAVE LESS OF A PASSIVE ROLE. WE
7 STILL CAN'T FORCE THEM TO.

8 DR. SADANA: THE REASON I ASK WHY CF
9 BECAUSE 25 PERCENT OF THE POPULATION CARRIES THE CF
10 GENE IN THE UNITED STATES. AND THOUGH THE
11 REFLECTION IS NOT LUCKILY FOUND THAT COMMON, STILL
12 IT'S PRETTY COMMON.

13 DR. MILLS: YEAH.

14 CHAIRPERSON YEE: THANK YOU. DR. QUICK.

15 DR. QUICK: YEAH. THANK YOU SO MUCH.
16 JUST TREMENDOUS RESULTS. I'M TRYING TO DO THE MATH
17 HERE. HOW MANY CLINICAL TRIALS HAS CIRM IN ITS
18 LIFETIME NOW GOTTEN UNDER WAY?

19 DR. MILLS: TWENTY-TWO.

20 DR. QUICK: TWENTY-TWO. SO ON AVERAGE,
21 THEN, IF I REMEMBER FROM YOUR PREVIOUS SLIDES, YOU
22 HAVE, WHAT, 300 TOTAL ENROLLEES IN TRIALS, SOMETHING
23 LIKE THAT, 350?

24 DR. MILLS: JUST UNDER 400.

25 DR. QUICK: SO SOMETHING LIKE, THEN, ON

BARRISTERS' REPORTING SERVICE

1 AVERAGE 20 ENROLLEES PER TRIAL IF I DO THE MATH.
2 THOUGHTS? I KNOW YOU SHOWED THE ACCELERATION CURVE.
3 THAT'S GREAT. BUT IN GENERAL, I'M NOT AN EXPERT IN
4 CLINICAL TRIALS, DO THOSE NUMBERS DISAPPOINT YOU?
5 ARE THOSE GREAT NUMBERS? I'M NOT SURE.

6 AND THEN MY FOLLOW-UP QUESTION TO THAT IS
7 I KNOW IN A NUMBER OF AREAS, ESPECIALLY AROUND
8 CANCER WHERE I'VE TALKED TO A NUMBER OF PEOPLE IN
9 THE FIELD, REALLY DIFFICULT FINDING THE APPROPRIATE
10 DISTRIBUTION OF, FOR EXAMPLE, ETHNICITIES, ETC., TO
11 GET PEOPLE TO ENROLL. ARE YOU SEEING THAT SAME KIND
12 OF PROBLEM HERE? IT MUST BE TOUGH TO DO WHEN YOU'RE
13 TALKING ABOUT ENDS THAT ARE THIS SMALL. BUT ANYWAY,
14 IF YOU COULD COMMENT ON THAT.

15 DR. MILLS: SO THE FIRST QUESTION IS A
16 GREAT ONE. AND THE METRIC THAT I'M SHOWING IS AN
17 EASILY RELATABLE METRIC AND SORT OF UNDERSTAND
18 PEOPLE AND PUT A PATIENT. YOU PEEL THE ONION BACK A
19 LITTLE BIT JUST LIKE YOU DID. SAY, WELL, WAIT A
20 MINUTE. A BETTER METRIC THAN WHETHER OR NOT
21 PATIENTS ENROLLED WOULD BE PERCENTAGE OF TRIAL
22 ENROLLED PER UNIT TIME BECAUSE OUR TRIALS VARY
23 WIDELY. WE HAVE BIG PHASE II-PHASE III TRIALS AND
24 HAVE LOTS AND LOTS AND LOTS OF PATIENTS GOING IN.
25 WE HAVE -- SOME OF THESE DISEASES ARE TINY, SO IT'S

BARRISTERS' REPORTING SERVICE

1 NOT UNCOMMON FOR US TO HAVE A SEVEN-PATIENT TRIAL, A
2 TEN-PATIENT TRIAL. SO OUT OF THAT 22, THERE'S ALL
3 KINDS OF -- THEY'RE JUST VERY, VERY DIFFERENT,
4 THEY'RE VERY DIFFERENT BEASTS. AND SO IT'S AN
5 EASILY TRANSLATABLE NUMBER, BUT IT'S PROBABLY NOT
6 THE MOST USEFUL NUMBER.

7 SO WHAT I'M HAPPY WITH IS THAT WHEN WE
8 LOOK AT WHAT WE EXPECTED THESE TRIALS TO ENROLL AT
9 AND HOW THEY'RE ENROLLING, IT'S CLOSER THAN -- WE'RE
10 PUTTING IN 4.49 PATIENTS A QUARTER. BETTER TO SAY
11 WE EXPECTED AND WE WERE HAPPY WHEN THESE PROGRAMS
12 SAID THEY WERE GOING TO ENROLL IN X PERIOD OF TIME
13 AND 77 PERCENT OF THEM ARE ON OR AHEAD OF SCHEDULE.
14 SO THAT'S MY THOUGHTS ARE ON THAT. BUT WE'RE
15 CONSTANTLY THINKING ABOUT HOW TO MEASURE THINGS
16 BETTER. SO IT'S ONE WE'LL THINK MORE ABOUT.

17 THE SECOND QUESTION --

18 DR. QUICK: HAD TO DO WITH SORT OF THE
19 TYPES OF ENROLLEES AND WHETHER THAT'S BEEN A
20 CHALLENGE LIKE WE'VE SEEN IN A LOT OF CLINICAL
21 TRIALS.

22 DR. MILLS: SO WE HAVE TWO THINGS THAT WE
23 MADE AVAILABLE TO ADDRESS THAT ISSUE. ONE OF THEM
24 IS OUR ALPHA CLINICS WHICH WERE SET UP. WE HAVE
25 THREE ALPHA CLINICS. THEY ALL HAD TO BE IN SOUTHERN

BARRISTERS' REPORTING SERVICE

1 CALIFORNIA. AND THOSE THREE ALPHA CLINICS ACTUALLY
2 HAVE 22 OF THEIR OWN CLINICAL TRIALS THAT ARE GOING
3 ON THAT AREN'T OURS. ACTUALLY SEVEN OF THEM ARE
4 OURS, BUT THE REST AREN'T. FIFTEEN ARE THEIRS. AND
5 ONE OF THE PURPOSES OF THAT ALPHA CLINIC WAS
6 ACTUALLY TO CREATE THIS NETWORK WHERE THEY WERE ABLE
7 TO SHARE DATA AND PATIENTS, AND THEY ACTUALLY HAVE
8 COMMON IRB'S. SO IF YOU'RE IN ONE OF THOSE CENTERS,
9 YOU'RE IN ALL OF THOSE CENTERS AND MAKE PATIENT
10 SHARING AVAILABLE EASIER.

11 THE SECOND THING WE DID -- SO I THINK
12 THAT'S HELPING IN THAT. THE SECOND THING WE DID WAS
13 WE MADE IT REALLY CLEAR THAT IF YOU WERE A
14 CALIFORNIA COMPANY AND YOU NEEDED TO GO OUTSIDE OF
15 THE STATE OF CALIFORNIA TO GET THE DEMOGRAPHIC
16 REPRESENTATION YOU NEED, YOU CAN DO THAT. AS LONG
17 AS THE TRIAL IS GOING ON IN CALIFORNIA, THAT'S FINE.
18 AND SO THAT HELPS. THERE ARE SOME DISEASES WHERE
19 YOU JUST CAN'T STAY IN CALIFORNIA AND EXPECT TO
20 ENROLL A TRIAL.

21 DR. QUICK: THANK YOU.

22 CHAIRPERSON YEE: OKAY. THANK YOU,
23 DR. QUICK. ANY OTHER COMMENTS, MEMBERS? VERY WELL.
24 THANK YOU VERY MUCH FOR THE PRESENTATION.

25 DR. MILLS: THANK YOU.

BARRISTERS' REPORTING SERVICE

1 CHAIRPERSON YEE: WE APPRECIATE IT.
2 LET ME JUST DO A RECAP HERE. I DON'T
3 BELIEVE THERE ARE ANY MEMBERS OF THE PUBLIC WHO WISH
4 TO COME FORWARD AND MAKE COMMENTS. OKAY. I THINK
5 BEFORE WE ADJOURN, I'D LIKE TO HAVE JUST SOME
6 INTRODUCTIONS OF THE REPRESENTATIVES WHO ARE HERE
7 FROM CIRM. WITH YOU, DR. MILLS.

8 DR. MILLS: DR. RANDY MILLS.

9 MS. SILVA-MARTIN: CHILA SILVA-MARTIN.

10 MR. HARRISON: JAMES HARRISON.

11 CHAIRMAN THOMAS: JON THOMAS, CHAIR OF THE
12 BOARD.

13 MS. BONNEVILLE: MARIA BONNEVILLE.

14 CHAIRPERSON YEE: VERY WELL. THANK YOU.
15 THANK YOU FOR THE PRESENTATIONS TODAY. WE LACKED A
16 QUORUM TODAY, BUT WE WILL RECEIVE ALL THE
17 PRESENTATIONS. WE DO HAVE AN ACTION PENDING FOR A
18 MEETING TO BE DETERMINED AT A LATER DATE TO ACCEPT
19 AND HOPEFULLY APPROVE THE AUDIT. AND SO WE WILL BE
20 BACK IN CONTACT WITH THE MEMBERS OF THE COMMITTEE TO
21 SET THAT TIME UP, HOPEFULLY BEFORE THE END OF THIS
22 CALENDAR YEAR. SO WITHOUT ANY FURTHER COMMENT, I
23 BELIEVE THAT THIS COMMITTEE IS ADJOURNED. THANK YOU
24 VERY MUCH.

25 (THE MEETING WAS THEN CONCLUDED AT 11:02 A.M.)

BARRISTERS' REPORTING SERVICE

REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE 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

SOUTHERN CALIFORNIA ASSOCIATION OF GOVERNMENTS
BOARD ROOM
818 WEST 7TH STREET, 12TH FLOOR
LOS ANGELES, CALIFORNIA
ON
OCTOBER 27, 2016

WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.



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