## 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

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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
	3
	-

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

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.

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
	6

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
L7	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
	7

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

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,

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	то нім.
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
	10
	·

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.

WHAT CIRM DOES, WE ACTUALLY HAVE A PRETTY BROAD PORTFOLIO. WE HAVE FIVE MAJOR ACTIVITIES THAT WE GET INVOLVED IN. THE LAST IS INFRASTRUCTURE. WE LITERALLY BUILD THINGS. WE HAVE 12 MAJOR RESEARCH FACILITIES, WE HAVE THREE WHAT WE CALL ALPHA CLINICS WHERE WE ACTUALLY TREAT PEOPLE WITH STEM CELL THERAPIES THAT ARE UNDERGOING CLINICAL TRIALS, WE HAVE AN IPS OR STEM CELL BANK THAT WE HAVE, WE HAVE A GENOMICS CENTER. WE JUST OPENED UP TWO VERY INTERESTING PIECES CALLED THE ACCELERATING AND THE TRANSLATING CENTER. SO THAT'S OUR INFRASTRUCTURE

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

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

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
	10

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

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
	15

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

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
	17

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

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

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
	20

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
	21

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
	22

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

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.

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.
	25

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,

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
	27

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.
	20

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.
	20

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
	30

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

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.
	32

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	тоо.
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
	22

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
	34
	J#

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

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
	26

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

	D, IIII TEIG TEIG TEIG DEIN TEE
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.
	38
	ı Jü

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
	39
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1
     FRUSTRATION TOO BECAUSE WE HAVE INVESTIGATORS THAT
 2
     HAVE ABSOLUTELY NO EXPERIENCE NAVIGATING THIS AREA
     TRYING TO NAVIGATE THIS AREA, AND THAT'S WHY WE PUT
 3
 4
     IN THAT ACCELERATING AND TRANSLATING CENTER. SO WE
 5
     COULD GIVE THEM THE HELP.
 6
               CHAIRPERSON YEE: ANOTHER QUESTION?
                DR. QUICK: DR. MILLS, THANK YOU SO MUCH.
 7
     CONGRATULATIONS TO YOU AND YOUR TEAM FOR ALL YOUR
 8
 9
     SUCCESSES.
               QUESTIONS. SO IF CIRM WAS TO GO OUT OF
10
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
     YOU FEEL YOU HAVE TO TELL RIGHT NOW?
14
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
     STORY ISN'T GOING TO BE ONE-OFF. THE REAL STORY IS
18
19
     GOING TO BE A CONTINUUM OF SUCCESS. AND THAT IS
20
     GOING TO BECOME MORE AND MORE APPARENT TO PEOPLE.
21
     CAN SEE IT NOW BECAUSE I'M INSIDE IT. I LIVE IT
22
     EVERY DAY. BUT IT'S NOT COMPLETELY APPARENT ON THE
     OUTSIDE. BUT IF YOU'LL HOLD THAT UNTIL THE CLINICAL
23
24
     PRESENTATION, I'LL SHOW YOU.
25
               DR. QUICK: OKAY. GREAT. THANK YOU.
                               40
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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
	41

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

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

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

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

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

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
	4-7

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

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

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

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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
     OUARTER. THAT MANY TRIALS -- BASICALLY THE WAY WE
     DESIGNED IT WAS WE KNOW, WE KNOW WE'RE GOING TO HAVE
10
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
     FALLOUT, BUT WE'RE GOING TO PUT 65 THINGS IN WITH
14
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.
               I'M NOT A -- I DON'T LIKE THE EMOTIONAL
18
19
     COMPONENTS OF IT. I'M AN EMOTIONAL PERSON.
     LIKE THE -- I'M MORE LIKE LET'S LET THE SCOREBOARD
20
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.
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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.

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
	F 2

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

1	IN AND INPUT THEM MANUALLY INTO FI\$CAL. 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 FI\$CAL 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
	r r

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

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,

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
	5,8

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

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

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
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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

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 FI\$CAL 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 FI\$CAL 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

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

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,
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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

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.

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

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
	CO

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.

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 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

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

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

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

PROGRAM.

1

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

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
	7.0

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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
     WHEN THERE ARE PROGRAMS THAT WE WANT, AND THEY'RE A
 4
 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.
               CHAIRPERSON YEE: THANK YOU. DR. QUICK.
14
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
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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 OF PATIENTS GOING IN.
25	WE HAVE SOME OF THESE DISEASES ARE TINY, SO IT'S

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
	70

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.
	80

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.)
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#### REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE PROCEEDINGS BEFORE THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD AT THE LOCATION INDICATED BELOW

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

Th C. Drawn

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