INDEPENDENT CALIFORNIA INS ORG	BEFORE THE CE SUBCOMMITTEE OF THE CITIZENS' OVERSIGHT COMMITTEE TO THE STITUTE FOR REGENERATIVE MEDICINE ANIZED PURSUANT TO THE TEM CELL RESEARCH AND CURES ACT REGULAR MEETING
LOCATION:	VIA ZOOM
DATE:	NOVEMBER 29, 2021 1 p.m.
REPORTER:	BETH C. DRAIN, CA CSR CSR. NO. 7152
FILE NO.:	2021-24
	CSR. NO. 7152

#### INDEX

ITEM DESCRIPTION	PAGE NO.
OPEN SESSION	
1. CALL TO ORDER.	3
2. ROLL CALL.	3
ACTION ITEMS	
3. CONSIDERATION OF AMENDMENTS TO THE SCIENCE SUBCOMMITTEE MISSION STATEMENT	4
4. CONSIDERATION OF FINAL DRAFT STRATEGIC PLAN FINAL DRAFT STRATEGIC PLAN	6
5. CONSIDERATION OF REVISED CIRM RESEARCH BUDGET FISCAL YEAR 2021-2022	47
DISCUSSION ITEMS	
6. PUBLIC COMMENT.	NONE
7. ADJOURNMENT.	53
2	

	BETH C. DRAIN, CA CSR NO. 7152
1	NOVEMBER 29, 2021; 1 P.M.
2	
3	CHAIRMAN GOLDSTEIN: LET ME CALL THE
4	MEETING TO ORDER AND ASK MARIA TO CALL THE ROLL.
5	MS. BONNEVILLE: HAIFA ABDULHAQ. ELENA
6	FLOWERS. MARK FISCHER-COLBRIE.
7	DR. FISCHER-COLBRIE: HERE.
8	MS. BONNEVILLE: JUDY GASSON.
9	DR. GASSON: HERE.
10	MS. BONNEVILLE: LARRY GOLDSTEIN.
11	CHAIRMAN GOLDSTEIN: HERE.
12	MS. BONNEVILLE: DAVID HIGGINS. PAT
13	LEVITT.
14	DR. LEVITT: HERE.
15	MS. BONNEVILLE: DAVID LO.
16	DR. LO: HERE.
17	MS. BONNEVILLE: DAVID MARTIN.
18	DR. MARTIN: HERE.
19	MS. BONNEVILLE: SHLOMO MELMED. CHRISTINE
20	MIASKOWSKI.
21	DR. MIASKOWSKI: HERE.
22	MS. BONNEVILLE: JONATHAN THOMAS.
23	CHAIRMAN THOMAS: HERE.
24	MS. BONNEVILLE: ART TORRES.
25	MR. TORRES: HERE.
	3

1	MS. BONNEVILLE: KRISTINA VUORI.
2	DR. VUORI: HERE.
3	MS. BONNEVILLE: KAROL WATSON. KEITH
4	ΥΑΜΑΜΟΤΟ.
5	DR. YAMAMOTO: HERE.
6	MS. BONNEVILLE: THANK YOU. WE HAVE A
7	QUORUM, LARRY.
8	CHAIRMAN GOLDSTEIN: FIRST ON THE AGENDA,
9	SUBCOMMITTEE MISSION STATEMENT. JUST AS BACKGROUND,
10	THIS IS A SLIGHTLY MODIFIED MISSION STATEMENT FROM
11	WHAT WAS USED A YEAR AGO. I MODIFIED IT TO MAKE IT
12	A LITTLE BIT CLEARER AND MORE SPECIFIC. J.T. HAS
13	HAD SOME INPUT ON IT. AND SO THE QUESTION IS DO ANY
14	MEMBERS OF THE SUBCOMMITTEE HAVE QUESTIONS ABOUT THE
15	WORDING OR CONCERNS?
16	I'M ASSUMING THAT THE SILENCE MEANS NO
17	CONCERNS OR QUESTIONS, NOT THAT NOBODY ELSE HAS READ
18	IT.
19	DR. MARTIN: WE'RE JUST ALL MUTED.
20	DR. VUORI: IT LOOKS GOOD TO ME, LARRY.
21	THANKS FOR THE WORK.
22	CHAIRMAN GOLDSTEIN: THANK YOU.
23	MR. TORRES: HAPPY HANUKKAH, LARRY.
24	CHAIRMAN GOLDSTEIN: THANK YOU. OKAY. IN
25	THE ABSENCE OF ANY ADDITIONAL QUESTIONS, CAN
	4

-	
1	SOMEBODY MOVE TO APPROVE?
2	MR. TORRES: MOVE IT.
3	DR. YAMAMOTO: SECOND.
4	CHAIRMAN GOLDSTEIN: OKAY. GOOD. THANK
5	YOU. ANY FURTHER QUESTIONS FROM THE SUBCOMMITTEE?
6	ANY PUBLIC COMMENT?
7	MS. BONNEVILLE: THERE ARE NO HANDS
8	RAISED.
9	CHAIRMAN GOLDSTEIN: MARIA, CAN YOU PLEASE
10	CALL THE ROLL.
11	MS. BONNEVILLE: HAIFA ABDULHAQ. ELENA
12	FLOWERS.
13	DR. FLOWERS: YES.
14	MS. BONNEVILLE: MARK FISCHER-COLBRIE.
15	DR. FISCHER-COLBRIE: AYE.
16	MS. BONNEVILLE: JUDY GASSON.
17	DR. GASSON: YES.
18	MS. BONNEVILLE: LARRY GOLDSTEIN.
19	CHAIRMAN GOLDSTEIN: YES.
20	MS. BONNEVILLE: DAVID HIGGINS. PAT
21	LEVITT.
22	DR. LEVITT: YES.
23	MS. BONNEVILLE: DAVID LO.
24	DR. LO: YES.
25	MS. BONNEVILLE: DAVID MARTIN.
	5
	2

	· ·
1	DR. MARTIN: YES.
2	MS. BONNEVILLE: SHLOMO MELMED. CHRISTINE
3	MIASKOWSKI.
4	DR. MIASKOWSKI: YES.
5	MS. BONNEVILLE: JONATHAN THOMAS.
6	CHAIRMAN THOMAS: YES.
7	MS. BONNEVILLE: ART TORRES.
8	MR. TORRES: AYE.
9	MS. BONNEVILLE: KRISTINA VUORI.
10	DR. VUORI: YES.
11	MS. BONNEVILLE: KAROL WATSON. KEITH
12	YAMAMOTO.
13	DR. YAMAMOTO: YES.
14	MS. BONNEVILLE: MOTION CARRIES.
15	CHAIRMAN GOLDSTEIN: OKAY. THANK YOU,
16	EVERYBODY.
17	NEXT UP ON THE AGENDA, FINAL DRAFT
18	STRATEGIC PLAN. MARIA MILLAN, CAN YOU WALK US
19	THROUGH YOUR THOUGHTS AND PRESENTATION PLEASE.
20	DR. MILLAN: THANK YOU, DR. GOLDSTEIN.
21	I'M GOING TO SHARE A SCREEN REALLY QUICKLY TO HELP
22	US WITH THIS DISCUSSION. I DON'T KNOW IF THIS IS
23	THE RIGHT ONE. I'M NOT SURE. YES, IT IS.
24	OKAY. MEMBERS OF THE ICOC SCIENCE
25	SUBCOMMITTEE, THANK YOU FOR THIS OPPORTUNITY TO GO
	6
	U

1	THROUGH THE DRAFT STRATEGIC PLAN. THE DRAFT PLAN
2	WAS CIRCULATED TO YOU PRIOR TO THANKSGIVING, AND I
3	KNOW IT WAS SHORT TURN-AROUND, BUT WE REALLY WANTED
4	FOR YOU TO SEE THIS PLAN. THERE'S STILL SEVERAL
5	ROUNDS OF COPY EDITING LEFT IN TERMS OF FINAL FIXING
6	OF TYPOS, STYLISTIC AND FORMATTING, BUT WE REALLY
7	WANTED THE CONTENT TO BE SOMETHING THAT YOU HAD A
8	CHANCE TO HAVE A LOOK AT. AND WE WANTED TO HAVE THE
9	OPPORTUNITY TO INCORPORATE ANY ADDITIONAL FEEDBACK
10	TO THE STRATEGIC PLAN PRIOR TO FINALIZING FOR THE
11	BOARD MEETING IN DECEMBER.
12	I DON'T KNOW IF YOU STILL CAN SEE MY
13	SCREEN.
14	CHAIRMAN GOLDSTEIN: WE COULD, YES.
15	DR. MILLAN: OKAY. PERFECT.
16	SO AS YOU CAN TELL FROM THE STRATEGIC
17	PLAN, WE REALLY DID DO A PRETTY COMPREHENSIVE
18	BACKGROUND ON CIRM, BACKGROUND ON THE LANDSCAPE, AS
19	WELL AS RATIONALE FOR THE PLAN, WHICH REALLY IS
20	ORGANIZED AROUND THREE MAJOR BROAD THEMES OF
21	ADVANCING WORLD-CLASS SCIENCE, DELIVERING REAL-WORLD
22	SOLUTIONS, AND PROVIDING OPPORTUNITY FOR ALL.
23	IN ADDITION TO EXPANDING THE MISSION
24	STATEMENT, WHICH WE WILL TALK ABOUT IN A LITTLE BIT,
25	WHAT WE HAVE DONE IS EMPHASIZED THE IMPORTANCE OF
	7

1	THE DELIVERY OF TREATMENTS AND ADVANCEMENTS THAT
2	ARISE FROM CIRM'S PROGRAMS IN THE UPCOMING YEARS TO
3	ALL PATIENTS IN NEED, INCLUDING DIVERSE AND
4	UNDERSERVED POPULATIONS. AND SO THIS WILL REQUIRE
5	KIND OF A NOVEL PARADIGM SHIFTING APPROACH BOTH TO
6	HOW WE SUPPORT AND ORGANIZE OUR SCIENTIFIC
7	INVESTMENTS AS WELL AS THE TYPE OF PROGRAMS WE CAN
8	DO TO FOSTER THE EXPERTISE AND THE WORKFORCE OF
9	TOMORROW AS WELL AS ADDRESS GAPS THAT THE FIELD
10	STILL HAS IN FRONT OF IT IN ORDER TO TRULY MAKE
11	THESE SCIENTIFIC DISCOVERIES SOMETHING THAT CAN
12	REACH PATIENTS.
13	SO THE THREE THEMES, JUST TO HIGHLIGHT,
14	AND THIS IS A SUMMARY OF WHAT YOU WILL SEE IN THE
15	STRATEGIC PLAN, IN THE THEME OF ADVANCING
16	WORLD-CLASS SCIENCE, THE GENERAL IDEA IS TO LEVERAGE
17	COLLECTIVE SCIENTIFIC KNOWLEDGE THAT'S GAINED FROM
18	ALL OF OUR SCIENTIFIC PROGRAMS AND ALSO TO HARNESS
19	THE HUGE AMOUNTS OF DATA THAT EMANATE FROM THESE
20	PROJECTS AND TO BRING THAT TO THE SCIENTIFIC
21	COMMUNITY VIA COLLABORATIVE PATHWAYS ORGANIZED IN
22	COMPETENCY HUBS AND KNOWLEDGE NETWORKS. AND WE GO
23	ON TO DESCRIBE WHAT THOSE WOULD LOOK LIKE, WHAT THE
24	INTENT IS, AND THE FORMAT FOR THIS.
25	THE IDEA BEHIND THIS IS TO TRULY FOSTER
	8

1	ORGANICALLY COLLABORATIVE SYNERGIES THAT WOULD
2	ADVANCE THE SCIENCE AND MAKE THE MOST OUT OF BOTH
3	BASIC TRANSLATIONAL RESEARCH AS WELL AS REVERSE
4	TRANSLATION WHERE LEARNINGS THAT WE HAVE FROM LATER
5	STAGE PROGRAMS WILL INFORM QUESTIONS THAT COULD BE
6	FURTHER RESEARCHED IN THE BASIC AND FUNDAMENTAL
7	FOUNDATIONAL STAGE OF SCIENCE.
8	THE SECOND CATEGORY IS TO DELIVER
9	REAL-WORLD SOLUTIONS. THE MAJOR GOAL IS TO ADVANCE
10	MORE THERAPIES SAFELY THROUGH FDA MARKETING APPROVAL
11	USING OUR WELL-ESTABLISHED PARTNERSHIP MODEL,
12	BUILDING ON THAT, AND COLLABORATING WITH REGULATORY
13	BODIES, INDUSTRY, AND ACADEMIC AND COMMUNITY
14	STAKEHOLDERS, INCLUDING HEALTHCARE DELIVERY SYSTEMS.
15	THE PROGRAMS THAT WE PROPOSE UNDER THAT
16	CATEGORY INVOLVE LEVERAGING OUR THERAPEUTICS
17	DEVELOPMENT PORTFOLIO APPROACH SO THAT WE ARE A
18	ONE-STOP SHOP IN TERMS OF OUR BROAD PORTFOLIO IN
19	DISCUSSIONS WITH STAKEHOLDERS, INCLUDING THE FDA,
20	AND THAT IS SOMETHING THAT IS ALREADY YOU WILL
21	HEAR ABOUT IN A LITTLE BIT. THERE ARE ALREADY
22	STRUCTURES FOR THESE VERY INNOVATIVE WAYS OF
23	APPROACHING THESE PROGRAMS FROM A PORTFOLIO
24	APPROACH.
25	THE OTHER PIECE IS FUNDING A MANUFACTURING
	9

1	NETWORK TO OVERCOME THE HURDLES THAT IS VERY WELL
2	KNOWN IN THE FIELD TOWARD BRINGING THESE PROGRAMS
3	ALL THE WAY THROUGH TOWARD COMMERCIALIZATION AND TO
4	PATIENTS, EXPAND OUR ALPHA CLINICS NETWORK, NOT JUST
5	IN NUMBER, BUT IN TERMS OF EXPERTISE AND ACTIVITIES,
6	AND DEVELOPING COMMUNITY CARE CENTERS OF EXCELLENCE
7	BASED ON THE NEEDS OF THE COMMUNITY.
8	THE THIRD THEME IS PROVIDING OPPORTUNITIES
9	FOR ALL. OPPORTUNITIES REGARDING TRAINING, ACCESS
10	TO RESEARCH OPPORTUNITIES FOR A DIVERSE AND HIGHLY
11	SKILLED POPULATION, AND TO DELIVER ACCESSIBLE
12	TREATMENTS TO A DIVERSE PATIENT COMMUNITY.
13	SO IN THAT CATEGORY WE DESCRIBE HOW WE
14	WOULD DO THAT WITH MULTIPLE ONRAMPS IN OUR EDUCATION
15	PROGRAMS AS WELL AS THE GOAL OF WORKING WITH OUR
16	ACCESSIBILITY AND AFFORDABILITY WORKING GROUP TO
17	CREATE A ROAD MAP FOR ACCESS AND AFFORDABILITY.
18	AT THE LAST MEETING THERE WAS A LOT OF
19	DISCUSSION ABOUT THE MISSION STATEMENT. ONE OF THE
20	MAIN POINTS THAT DR. YAMAMOTO MADE IS TO MAKE SURE
21	THAT WE DON'T FORGET THE IMPORTANCE OF BASIC SCIENCE
22	AS WE ARE DRIVING TRANSLATION TOWARD THE CLINICS.
23	AND IT'S VERY CLEAR WE DON'T FORGET ABOUT THAT
24	BECAUSE ACCELERATING WORLD-CLASS SCIENCE IS THE VERY
25	FIRST THING THAT COMES UP IN THE MISSION STATEMENT.
	10

10

1	IT ALL STARTS WITH STRONG SCIENCE. AND YOU WILL SEE
2	IN THE STRATEGIC PLAN THAT IT REALLY DOES HIGHLIGHT
3	HOW WE WILL CONTINUE TO COMMIT TO FUNDING BASIC AND
4	FOUNDATIONAL RESEARCH, ORGANIZING IN A MORE
5	EFFICIENT WAY BOTH FOR ELUCIDATING DISEASE
6	MECHANISMS AND UNDERLYING CREATING WAYS TO
7	ELUCIDATE DISEASE PATHOLOGY AS WELL AS POTENTIAL
8	CURES, BUT ALSO TO CONTINUE TO FUND TRANSLATIONAL
9	AND CLINICAL RESEARCH SO THAT WE CAN DELIVER
10	TRANSFORMATIVE REGENERATIVE MEDICINE TREATMENTS TO A
11	DIVERSE CALIFORNIA AND WORLDWIDE IN AN EQUITABLE
12	MANNER.
13	SO THIS IS THE INITIAL DRAFT, NEAR FINAL
14	FORMAT OF THE MISSION STATEMENT THAT YOU RECEIVED
15	BASED ON A VERY STRONG FEEDBACK FROM THE BOARD THAT
16	THERE SHOULD BE A MUCH MORE DELIBERATE STATEMENT OF
17	THE IMPORTANCE OF DIVERSITY AND EQUITY IN THE
18	MISSION STATEMENT.
19	SINCE THIS TIME, WE HAD EXCELLENT FEEDBACK
20	FROM THE BOARD TO JUST MAKE IT NOT TO CHANGE THE
21	CONTENT, BUT TO JUST MAKE IT MORE TIGHT IN TERMS OF
22	A MISSION STATEMENT. SO AT THE TOP IS THE MISSION
23	STATEMENT YOU SEE IN THE DRAFT PLAN, ACCELERATING
24	WORLD-CLASS SCIENCE, TO DELIVER TRANSFORMATIVE
25	REGENERATIVE MEDICINE TREATMENTS TO A DIVERSE
	11

11

-	
1	CALIFORNIA AND WORLDWIDE IN AN EQUITABLE MANNER.
2	AND WE AGREED WITH THE FEEDBACK WE RECEIVED, THAT WE
3	SHOULD EDIT THIS TO STILL RETAIN THE SAME MEANING,
4	BUT BE MORE REFLECTIVE OF OUR INTENT, TO EDIT THIS
5	TO SAY ACCELERATING WORLD-CLASS SCIENCE, TO DELIVER
6	TRANSFORMATIVE REGENERATIVE MEDICINE TREATMENTS IN
7	AN EQUITABLE MANNER TO A DIVERSE CALIFORNIA AND
8	WORLD.
9	I'M GOING TO PAUSE THERE. THIS WAS A
10	POINT OF A LOT OF DISCUSSION AT THE LAST BOARD
11	MEETING. SO I WANTED TO MAKE SURE WE HAD AN
12	OPPORTUNITY TO DISCUSS THE MISSION STATEMENT. DR.
13	GOLDSTEIN.
14	CHAIRMAN GOLDSTEIN: SURE. ANYBODY HAVE
15	CONCERNS, SUGGESTIONS, OR QUESTIONS ABOUT THE
16	MISSION STATEMENT?
17	DR. MARTIN: ONE OF THE THINGS THAT I
18	THINK IS REALLY IMPORTANT FOR CIRM, SINCE WE ARE
19	ACTUALLY A SMALL ENTITY OR SMALL FRACTION OF ALL OF
20	THE REGENERATIVE MEDICINE SCIENCE GOING ON IN THE
21	WORLD, IS TO NOT JUST ACCELERATE IT, BUT TO EXPAND
22	IT. I NOTICE THE WORD "EXPLODE" IS IN THERE.
23	SCALING IT. AND WHAT MARIA'S FIRST SLIDE SHOWED,
24	SECOND SLIDE ACTUALLY, IS THE ACTIVITIES THAT WE
25	WANT OR WHAT WE WANT TO EXPAND OR SCALE.

12

1	AND SO I JUST WONDER WHETHER THE WORD
2	"SCALE" OR "EXPANSION," ACCELERATE AND EXPAND
3	WORLD-CLASS SCIENCE OR THE APPLICATION OF SCIENCE,
4	FOR EXAMPLE. BUT I ALSO WONDER WHETHER WE WOULD
5	BENEFIT FROM HAVING AN OVERVIEW OF WHAT OUR STRATEGY
6	IS. BECAUSE IN A WAY THERE ARE ALWAYS DISCUSSIONS
7	ABOUT WHAT STRATEGY AND WHAT ARE LOGISTICS, ET
8	CETERA, AND THERE'S NO VERY CLEAR DISTINCTIONS, I
9	THINK. I JUST WONDER ABOUT IN THE STRATEGY
10	SOMETHING ABOUT SCALING THE UNIQUE FEATURES,
11	CAPABILITIES, AND ACHIEVEMENTS OF CIRM. BY SCALING,
12	I MEAN EXPANDING. AND SO WE WANT TO HAVE A BIG
13	IMPACT IN NOT JUST CALIFORNIA, BUT THE WORLD. AND
14	SO ACCELERATING IS IMPORTANT, BUT ALSO FIGURING OUT
15	HOW TO EXPAND IT.
16	AND ONE OF THE WAYS THAT I'M VERY
17	ENTHUSIASTIC ABOUT IS THE EDUCATIONAL PROCESSES.
18	THAT'S A GREAT WAY TO EXPAND OR SCALE.
19	THOSE ARE JUST SOME THOUGHTS ABOUT WHAT WE
20	ARE TRYING TO DO, WHAT IS OUR STRATEGY IN TWO
21	SENTENCES AND THEN GET RIGHT INTO THE THREE PILLARS,
22	IF YOU WILL, THAT MARIA SHOWED.
23	DR. MILLAN: DR. MARTIN, IF YOU LOOK AT
24	THE I DON'T HAVE IT IN FRONT OF ME. MAYBE MARIA
25	CAN POINT TO IT. JUST BEFORE THE MISSION STATEMENT
	13

-	
1	IN THE STRATEGIC PLAN IN A BLUE BOX, THERE'S
2	ACTUALLY A STATEMENT OF WHAT THE A STATEMENT OF
3	THE STRATEGY. AND I UNDERSTAND IT DOESN'T SAY
4	EXPAND, BUT I THINK IT'S IMPLICIT IN THE FACT THAT
5	THERE'S MORE INVESTMENT INTO THE PROGRAMS THAT WE
6	DESCRIBE WE'RE GOING TO FUND THE PROGRAMS. AGAIN,
7	THE EDUCATIONAL PROGRAMS ARE A VERY CLEAR STATED
8	MISSION. SO THAT WILL DEFINITELY IS SOMETHING
9	THAT IT WILL DO.
10	AND I THINK A STATEMENT THAT WAS MADE AT
11	THE LAST MEETING IS THAT MISSION STATEMENT CRAFTING
12	IS SOMETHING THAT IT CANNOT BE COMPLETELY
13	COMPREHENSIVE, BUT WHAT WE REALLY WANT TO DO IS MAKE
14	SURE THAT WE CAPTURE THE ESSENCE OF WHY WE'RE HERE
15	AND WHAT IS IT AND HOW DO WE KNOW THAT WE
16	SUCCEEDED IF WE'VE DONE THIS? AND SO THAT IS,
17	ALTHOUGH IT DOESN'T I HAVE TO SAY WE MUST HAVE
18	GOTTEN A WHOLE LOAD OF DIFFERENT SUGGESTIONS ON THIS
19	MISSION STATEMENT. AND ALTHOUGH WE'D LIKE TO BE
20	ABLE TO DO EVERYTHING, UNFORTUNATELY I DON'T THINK
21	IT'S POSSIBLE. I THINK THE THING IS IT EMPHASIZES
22	THE SCIENCE, IT EMPHASIZES IN TERMS OF TREATMENTS TO
23	PATIENTS, IT EMPHASIZES EQUITY AND DIVERSITY, AND
24	EDUCATION, BUILDING UP MANUFACTURING IN PUBLIC
25	PRIVATE PARTNERSHIPS, BUILDING OF HEALTHCARE

14

-	
1	SYSTEMS. THOSE ARE THE HOW-TOS. AND SO THOSE ARE
2	ALL EMBEDDED IN OUR STRATEGY.
3	SO I HOPE THAT THAT REASSURES YOU.
4	CERTAINLY WE CAN POTENTIALLY ADD WORDING IN THE
5	DESCRIPTION OF THE STRATEGY AS STATED IN THE BLUE
6	BOX PRIOR TO THE MISSION STATEMENT THAT SPEAKS TO
7	HOW THIS WOULD EXPAND BOTH KNOWLEDGE AND PROGRAMS BY
8	DOING THIS.
9	DR. MARTIN: I AGREE.
10	CHAIRMAN GOLDSTEIN: OKAY. GOOD. THEN
11	LET'S PROCEED PLEASE.
12	DR. MILLAN: OKAY. SEE IF I CAN MOVE
13	THESE SLIDES NOW.
14	SO IN TERMS OF THEME ONE, ONE OF THE
15	STATEMENTS I THINK MADE BY DR. GOLDSTEIN IS THAT WE
16	REALLY NEED TO MAKE SURE THAT WE CONTINUE TO REMAIN
17	TRUE TO OUR COMMITMENT, THAT WE ARE NOT AFRAID OF
18	RISKS, THAT THE SCIENCE IS THERE. SO TO CONTINUE TO
19	FUND HIGH-RISK, HIGH-REWARD RESEARCH PROJECTS, THAT
20	THIS IS UNIQUE TO CIRM. AND WE WILL CONTINUE TO DO
21	THIS BY WAY OF OUR EXISTING FUNDING PROGRAM
22	ANNOUNCEMENTS AS WELL AS FUTURE ANNOUNCEMENTS, THAT
23	THIS WILL NOT BY ANY STRETCH LIMIT THE TYPE OF BOLD
24	PROGRAMS THAT WE WILL FUND IF THE SCIENCE MAKES
25	SENSE AND IT HAS VALUE.

1	IN ADDITION, WE WANT AS YOU CAN TELL
2	FROM THE PLAN, A LOT OF THE NARRATIVE IS AROUND THE
3	RATIONALE FOR BUILDING DATA INFRASTRUCTURE, TO
4	DEMOCRATIZE DATA THROUGH KNOWLEDGE NETWORKS, AND THE
5	ACCELERATION OF SCIENCE AND MAYBE THE EXPANSION OF
6	THOSE PROGRAMS THROUGH THE USE OF THESE
7	COLLABORATIVE PATHWAYS VIA COMPETENCY HUBS. SO THAT
8	IS SOMETHING THAT IS A VERY IMPORTANT AND EMPHASIZED
9	PART OF THE STRATEGIC PLAN.
10	ONE OF THE THINGS THAT WAS BROUGHT UP BY
11	MANY BOARD MEMBERS, DR. GASSON, I THINK, STEVE
12	JUELSGAARD, MANY OTHERS WAS THAT WHERE IS CNS IN
13	THERE BECAUSE THERE WAS \$1.5 BILLION SPECIFICALLY
14	MENTIONED IN PROP 14. WE STATED IN THE PLAN THAT
15	THIS GENERAL TEMPLATE OF ENABLING COLLABORATIVE AND
16	CONSORTIUM RESEARCH, THAT THE FIRST FOCUS WILL BE ON
17	CNS. AND SO IT'S NOT THAT IT'S EXCLUSIVE TO CNS,
18	BUT IT WILL BE DESIGNED TO ENABLE INTEGRATED
19	RESEARCH AND ACTIVITIES AROUND CNS.
20	SO AS I'LL REMIND THE BOARD, THE FUNDING
21	THAT GOES TO CNS IN GENERAL ORGANICALLY DOES
22	CALCULATE TO APPROXIMATELY THAT MUCH OF THE TOTAL
23	BOND FUNDING EVEN IN PROP 71. HOWEVER, WHAT WE WANT
24	TO DO IS LEVERAGE THAT FUNDING AND GAIN AS MUCH,
25	EXTRACT AS MUCH VALUE FROM THE FUNDING INVESTMENT WE
	16

16

1	PUT INTO THOSE PROGRAMS VIA THE STRUCTURE THAT WE'RE
2	PROPOSING IN THE STRATEGIC PLAN, CREATION OF
3	KNOWLEDGE NETWORKS, COMPETENCY HUBS, AND TEAM
4	SCIENCE.
5	SO I'M GOING TO STOP THERE FOR ANY BOARD
6	INPUT, DISCUSSION, OR QUESTIONS ON THAT TOPIC.
7	DR. GASSON: SO I WOULD JUST MAKE A
8	COMMENT, THAT THE PAST FUNDING UNDER PROP 71, IN MY
9	UNDERSTANDING, WAS PRIMARILY FOR NEURODEGENERATIVE
10	DISORDERS. IT WAS SPINAL CORD, PARKINSON'S, THOSE
11	TYPES OF THINGS. WHEREAS, THE NEW \$1.5 BILLION, IF
12	I UNDERSTAND CORRECTLY, IS AIMED MORE TOWARD
13	NEUROPSYCHIATRIC DISORDERS, WHICH IS AN AREA OF
14	TREMENDOUS UNMET NEED.
15	AND I THINK YOU'VE DONE A CONSIDERABLE
16	AMOUNT OF WORK IN PLANNING AHEAD FOR THAT, BUT I
17	JUST WANTED TO MAKE THAT ONE DISTINCTION.
18	DR. MILLAN: THANK YOU, DR. GASSON. I
19	THINK IT INCLUDES NEUROPSYCHIATRIC, BUT IT'S BROAD
20	CNS. THERE IS INCLUSION IN THE TEXT ABOUT HOW EARLY
21	THAT FIELD IS, BUT THAT WE BELIEVE THAT SOME OF THE
22	PROGRAMS THAT WE ARE ENVISIONING, SUCH AS SHARED
23	MODELS FOR STUDYING NEUROPSYCHIATRIC DISEASE, SUCH
24	AS CELL MODELS AND GENE EDITABLE CELLS AND STEM
25	CELLS, AND GENOMICS INFORMATION AND OTHER TYPES OF
	17

17

ĺ	
1	DATA THAT COME FROM THAT WILL BE SOMETHING THAT WILL
2	BE ESSENTIAL FOR THAT AREA OF RESEARCH.
3	MR. TORRES: I JUST WANT TO REITERATE ON
4	THAT POINT, TO JUDY'S POINT, AND THAT AS ONE OF THE
5	AUTHORS, AS WE MOVE FORWARD, THAT WAS THE INTENT, TO
6	MAKE SURE THAT WE DIDN'T IGNORE THIS WHOLE AREA
7	BECAUSE IT HAS BEEN FOR THE MOST PART. AND IF WE
8	CAN PROVIDE SOME KIND OF CONTRIBUTION FOR THE
9	FUTURE, THAT'S WHAT THE INTENT OF PROPOSITION 14
10	WAS.
11	DR. MILLAN: THANK YOU, ART.
12	SO WE HAVE ACCOUNTED FOR THAT AS MENTIONED
13	SPECIFICALLY IN THE STRATEGIC PLAN. AND WE DO
14	BELIEVE THAT THE PROGRAMS THAT ARE BEING SET UP WILL
15	DEFINITELY GO A LONG WAY.
16	I WANTED TO CALL YOUR ATTENTION IN NATURE
17	CELL BIOLOGY AN ARTICLE CAME OUT JOINTLY AUTHORED BY
18	MYSELF, THE ALLEN INSTITUTE, AND EKEMINI RILEY FROM
19	THE COALITION FOR ALIGNING SCIENCES, SPEAKING TO THE
20	IMPORTANCE OF BUILDING DIVERSE CELL MODELS AND
21	SHARED CELLS AND CELL MODELS. WE WILL SEND A COPY
22	OF THAT. THERE'S OPEN ACCESS TO IT. WE'LL SEND A
23	LINK. SO THERE IS GREAT INTEREST AND A SHARED
24	DESIRE TO BE ABLE TO CREATE THESE TYPE OF RESOURCES
25	FOR ALL THE VARIOUS AREAS WE ARE TALKING ABOUT,

18

1	INCLUDING NEUROPSYCHIATRIC.
2	DR. LEVITT: MARIA, JUST ONE COMMENT ON
3	THE SECOND BULLET. EACH OF THE BULLETS HAS AN
4	ACTION VERB. THE FIRST ONE IS CONTINUE, AND IT'S
5	CLEAR WHAT THAT MEANS. THE THIRD ONE IS DEPLOYMENT.
6	THAT'S AN ACTION ITEM. THE SECOND ONE, DESIGN
7	SORRY. I'M BY CHILDREN'S HOSPITAL.
8	THE SECOND ONE, DESIGN IS SOMETHING YOU
9	DESIGN, BUT NOT NECESSARILY DEPLOY OR IMPLEMENT.
10	AND THERE'S A WORD YOU USE ON ANOTHER PAGE, PAGE 12,
11	DEVELOP NEXT GENERATION. I WOULD EVEN SUBSTITUTE
12	DESIGN FOR DEVELOP INFRASTRUCTURE THAT ORGANIZES AND
13	DEMOCRATIZES. THE REASON I SAY THAT IS BECAUSE THEN
14	IT BECOMES NOT IMPLICIT, BUT ACTUALLY VERY CLEAR
15	THAT THERE'S GOING TO BE AN IMPLEMENTATION OF
16	INFRASTRUCTURE AND DATA DEMOCRATIZATION THAT'S GOING
17	TO REQUIRE SOP'S AND OTHER SORTS OF THINGS TO MAKE
18	SURE THAT THESE BECOME REALLY SHARED DISTRIBUTIVE
19	RESOURCES.
20	DR. MILLAN: THANK YOU SO MUCH. I'LL MAKE
21	SURE I KNOW THAT THE TEAM IS REALLY TAKING NOTES,
22	AND WE'LL MAKE SURE THAT THAT SO THIS IS JUST MY
23	PARAPHRASING. SO I MAY HAVE NEGLECTED TO USE THE
24	WORDING WE HAD IN THE STRATEGIC PLAN ITSELF, BUT WE
25	WILL ENSURE THAT IT'S MORE ACTIVE AND DELIBERATE IN

19

20

1	OUR PROGRAMS THROUGH ADVISORY PANELS, THE CLINICAL
2	ADVISORY PANELS, AND WE ALSO EXTENDED THAT TO
3	TRANSLATIONAL ADVISORY PANELS. IN THIS WAY WE ARE
4	ABLE TO REALLY TAKE A PORTFOLIO APPROACH FOR HOW WE
5	ADVISE OUR PROGRAMS ALTHOUGH THEY'RE VERY, VERY
6	DIFFERENT, BUT JUST A GENERAL APPROACH OF ENSURING
7	THAT WE REALLY ARE ALIGNED AND INFORMED BY THE NEEDS
8	THAT THEY BY THE FDA REQUIREMENTS AND THE TYPES
9	OF PROGRAM NEEDS THAT WILL NEED TO BE IN PLACE IN
10	ORDER FOR THEM TO BE ABLE TO MOVE DOWN THE
11	COMMERCIALIZATION PATH.
12	OUR HEAD OF OUR THERAPEUTIC DEVELOPMENT
13	PROGRAM, DR. ABLA CREASEY, ENVISIONS THAT THIS
14	ADVISORY PANEL AND PORTFOLIO APPROACH CAN ACTUALLY
15	BE MOVED TO THE NEXT LEVEL WHERE WE BRING IN
16	ADDITIONAL EXPERTISE AND RESOURCES SO THAT WE CAN
17	HELP OUR PROGRAMS REALLY IDENTIFY KEY BOTTLENECKS
18	TOWARD MARKETING APPROVAL AND THEN ALSO ANTICIPATE
19	THE POSTMARKETING STRATEGIES.
20	SO WE HAVE BEEN IN DISCUSSION WITH
21	DIFFERENT GROUPS. THERE'S A LOT OF INTEREST IN
22	INCLUDING SOME OF THE INITIATIVES OUT THERE, SUCH AS
23	THE BESPOKE INITIATIVE THAT NIH AND FDA ARE JOINTLY
24	COLLABORATING ON. WE ARE DISCUSSING WITH THEM THE
25	POSSIBILITY OF HAVING A MORE FORMAL RELATIONSHIP SO
	21

21

1	THAT WE CAN ALL LOOK AT OUR PROGRAMS TOGETHER. IN
2	THIS CASE IT'S FOR RARE DISEASE WITH AAV RELATED
3	GENE DELIVERY, BUT THAT WOULD BE A FIRST
4	DEMONSTRATION CASE OF KIND OF A PORTFOLIO APPROACH.
5	AND DR. CREASEY IS LEADING THAT DISCUSSION. WE WILL
6	REPORT BACK WITH MORE SOON.
7	SO THAT IS NOT NECESSARILY A NEW CONCEPT
8	PROPOSAL. IT'S HOW WE ARE LEVERAGING WHAT WE
9	ALREADY DO AND CREATING NEW PROGRAMS AND BRINGING
10	OPPORTUNITIES FORWARD FOR KEY PARTNERSHIPS IN
11	NAVIGATING THE REGULATORY PATH AS WELL AS
12	ANTICIPATING HURDLES TOWARD MARKETING APPROVAL.
13	ANY QUESTIONS ON THAT? IN ADDITION
14	DR. VUORI: SORRY, MARIA. I WAS SLOW IN
15	GETTING OFF MUTE.
16	IN THE PREVIOUS SLIDES I'M WONDERING HOW
17	MUCH CIRM IS INVOLVED IN REIMBURSEMENT
18	CONVERSATIONS, ESPECIALLY AS IT COMES TO SORT OF
19	POTENTIAL ONE-OFF CURATIVE TREATMENTS. IS THAT
20	SOMETHING THAT CIRM WILL PARTICIPATE IN?
21	DR. MILLAN: I EXPECT THAT THAT'S
22	SOMETHING THAT'S GOING TO BE TAKEN UP IN PARTNERSHIP
23	WITH THE AAWG IN TERMS OF PAYMENT MODELS AND
24	REIMBURSEMENT AND PATIENT ASSISTANCE.
25	BUT YOU DO RAISE A QUESTION THAT WAS
	22
	۷۷ ک

1	BROUGHT UP BEFORE ABOUT HOW I FORGOT WHO BROUGHT
2	IT UP HOW WILL CIRM HANDLE THINGS SUCH AS
3	EXTENDED ACCESS AND THOSE TYPE OF WAYS THAT THE
4	PATIENTS MAY RECEIVE TREATMENTS PRIOR TO APPROVAL.
5	AND BY HAVING THESE MECHANISMS AND FORMATS FOR
6	INTERACTING WITH THE FDA AND THE REGULATORY BODIES,
7	I THINK THAT WE WILL HAVE MORE OF AN OPPORTUNITY TO
8	WORK THROUGH THAT TOGETHER. IT'S KIND OF RELATED.
9	THE REIMBURSEMENT WILL COME WITH THE ROAD MAP TOWARD
10	ACCESSIBILITY AND AFFORDABILITY.
11	DR. MELMED: I THINK THE QUESTION THAT'S
12	BEEN ASKED, MARIA, IS NOT FDA BUT CNS.
13	DR. MILLAN: SO THAT WOULD BE SOMETHING
14	THAT WOULD HAVE TO BE I THINK THAT'S DR. MELMED;
15	IS THAT RIGHT?
16	DR. MELMED: CORRECT. YEAH.
17	DR. MILLAN: HELLO. I THINK THAT THAT'S
18	SOMETHING THAT'S GOING TO HAVE TO BE DISCUSSED
19	WITHIN THE ACCESSIBILITY AND AFFORDABILITY WORKING
20	GROUP. AND WE WILL HAVE AN INTERNAL TEAM OF MEDICAL
21	AFFAIRS AND POLICY WHO WILL WORK WITH ACCESSIBILITY
22	AND AFFORDABILITY WORKING GROUP TO ENSURE THAT WE
23	COME UP WITH A ROAD MAP FOR HOW WE HAVE THE
24	DISCUSSIONS AND GET INFORMED IN TERMS OF HOW WE WORK
25	THROUGH THOSE PARTICULAR ISSUES.

1	DR. MELMED: THAT SOUNDS VERY RATIONAL,
2	BUT JUST IN THE SECOND BULLET TO ADD STAKEHOLDERS,
3	FDA, AND PAYORS.
4	DR. MILLAN: YES.
5	DR. MELMED: THIS IS A HIGH LEVEL PLAN,
6	AND SHOULD DEVOLVE DOWN TO THE OTHER COMMITTEES, BUT
7	I THINK THAT THE POINT THAT WAS RAISED IS VERY
8	IMPORTANT.
9	DR. MILLAN: THANK YOU. THAT'S A VERY
10	GOOD POINT. I'M LOOKING AT THIS AND YOU'RE
11	RIGHT. IN TERMS OF THE SPIRIT OF IT, THAT WOULD
12	ACTUALLY BE MAYBE IT'S NOT SOMETHING THAT WILL BE
13	CARRIED OUT BY THE THERAPEUTICS DEVELOPMENT TEAM PER
14	SE, BUT IT'S RELATED TO THE PROGRAMS BEING
15	DEVELOPED.
16	DR. MELMED: PAYORS WITH AN O, NOT PAYERS.
17	DR. MILLAN: YES. THAT'S MY NEW JERSEY
18	ACCENT. I SPELL IT O. THANK YOU.
19	DR. MELMED: IT'S O.
20	DR. MILLAN: I KNOW THAT.
21	CHAIRMAN GOLDSTEIN: INTERESTING
22	DISCOVERY. LET'S PROCEED.
23	DR. MILLAN: ALL RIGHT. WE'LL MAKE SURE
24	TO ADD THAT.
25	AND SO THE ALPHA CLINICS EXPANSION AND
	24

1	COMMUNITY CARE CENTERS OF EXCELLENCE ARE ITEMS THAT
2	ARE SPECIFICALLY MENTIONED IN PROPOSITION 14. THE
3	STRATEGIC PLAN OUTLINES THE IDEA BEHIND ALPHA
4	CLINICS EXPANSION, NOT JUST IN TERMS OF CAPACITY,
5	BUT IN TERMS OF EXPERTISE AND RESOURCES, INCLUDING
6	COMPETENCY HUBS FOR CLINICAL RESEARCH AND HEALTHCARE
7	DELIVERY.
8	IN ADDITION, THERE WAS A I THINK DR.
9	GOLDSTEIN AND OTHERS HAD MENTIONED THAT IT WAS SO
10	IMPORTANT TO CREATE OPPORTUNITIES FOR BASIC SCIENCE
11	REALLY TO HAVE EXPOSURE TO CLINICAL RESEARCH AND TO
12	THE CONSIDERATIONS AND THE COMMUNITY AND WITH
13	PATIENTS. AND THIS WILL BE ANOTHER IN ADDITION
14	TO OUR EDUCATION PROGRAMS, WHICH PROVIDE THAT TYPE
15	OF ENGAGEMENT AND THOSE OPPORTUNITIES, EXPANSION OF
16	THESE HEALTHCARE INFRASTRUCTURE AND THE ALPHA
17	CLINICS EXPANSION, AS WELL AS THE FUTURE COMMUNITY
18	CARE CENTERS WILL PROVIDE AN EXPOSURE AND TRAINING
19	GROUND FOR STUDENTS AND SCIENTISTS TO INTERACT. AND
20	THAT IS SOMETHING WE DO ANTICIPATE BUILDING INTO IT.
21	IN ADDITION, THESE PROGRAMS WILL PROVIDE A
22	SETTING FOR WORKFORCE DEVELOPMENT. AT THE LAST
23	MEETING IT WAS MENTIONED THAT WE ADDRESS THE ISSUE
24	OF WORKFORCE, A GAP IN TRAINED WORKFORCE FOR
25	MANUFACTURING, BUT THERE'S ALSO A GAP IN TERMS OF

25

1	CLINICAL RESEARCH AND THE SUPPORT ROLES IN CLINICAL
2	RESEARCH. AND THESE PROGRAMS, ESPECIALLY THE ALPHA
3	CLINICS EXPANSION, AS THE FIRST ONE, WILL HAVE THESE
4	OPPORTUNITIES FOR TRAINING OF NURSES AS WELL AS
5	CLINICAL TRIAL COORDINATORS AND OTHERS TYPES OF
6	SPECIALISTS AND ANCILLARY TYPES OF PROGRAMS THAT
7	COULD SUPPORT CLINICAL TRIALS.
8	CHAIRMAN THOMAS: MARIA, I KNOW WE TOUCHED
9	ON THIS A BIT AT THE LAST DISCUSSION, BUT COULD YOU
10	JUST, AGAIN, FOR THE BENEFIT OF THE SUBCOMMITTEE
11	HERE, LAY OUT THE PROCESS AND TIMELINE TO IMPLEMENT
12	THE COMMUNITY CARE CENTERS OF EXCELLENCE COMPONENT
13	OF THIS?
14	DR. MILLAN: SO OF THE TWO, THE ALPHA
15	CLINICS EXPANSION WILL PRECEDE THE COMMUNITY CARE
16	CENTERS BECAUSE THERE'S ALREADY AN ESTABLISHED
17	PROGRAM. AND THEN WHAT WILL HAPPEN IS THAT THAT
18	ALSO WILL PROVIDE OPPORTUNITIES FOR LINKAGES TO
19	FUTURE COMMUNITY CARE CENTERS.
20	MARIA BONNEVILLE AND TEAM ARE PLANNING
21	ADDITIONAL OUTREACH IN THE UPCOMING YEAR SO THAT WE
22	CAN BE BEST INFORMED IN TERMS OF HOW WE DESIGN THE
23	COMMUNITY CARE CENTERS, THE TYPES OF PROGRAMS THAT
24	IT INVOLVES, THE TYPE OF RESOURCES THAT WOULD BE
25	EMBEDDED IN THESE COMMUNITY CARE CENTERS, THE TYPE
	26

26

1	OF SPECIALTIES THAT WOULD BE INVOLVED OR NEED TO BE
2	GROWN IN ORDER TO TRULY SUPPORT AND ADDRESS THE
3	NEEDS OF THE COMMUNITY.
4	SO THAT WILL BE SOMETHING THAT WILL STILL
5	BE IN THE DEVELOPMENT PHASE THROUGH NEXT YEAR, AND
6	WE DON'T EXPECT THAT THAT WILL ROLL OUT TILL
7	PROBABLY THE FOLLOWING YEAR. BUT THE IDEA IS THAT
8	THIS WOULD BE SOMETHING THAT'S IMPLEMENTED WITHIN
9	THE FIVE-YEAR STRATEGIC PLAN AND WITHIN THE
10	PARAMETERS AS PROVIDED FOR BY PROP 14.
11	DR. MELMED: MARIA, CAN I EXTEND THAT
12	QUESTION? THIS SLIDE IS A LITTLE BIT UNCLEAR TO THE
13	INITIAL READER IN THAT WE'RE TALKING ABOUT RESEARCH
14	AND WE ARE TALKING ABOUT DELIVERY OF CARE. OR ARE
15	WE TALKING ABOUT CLINICAL TRIALS? AND IT'S NOT
16	CLEAR FROM THE SLIDE WHAT WE ARE TALKING ABOUT.
17	ALPHA CLINICS IS CLEARLY RESEARCH.
18	COMMUNITY CARE CENTERS, ARE WE TALKING ABOUT
19	DELIVERING CARE OR PARTICIPATING IN CLINICAL TRIALS?
20	BECAUSE IT'S NOT ARTICULATED ON THE SLIDE. SERVING
21	THE NEEDS COULD BE AND IF IT IS SERVING THE
22	NEEDS, THEN IT SHOULD NOT JUST BE COMMUNITY CARE
23	CENTERS. IT SHOULD BE SERVING THE NEEDS TO ALL OF
24	CALIFORNIA. BUT IS IT JUST CLINICAL TRIAL
25	PARTICIPATION OR ACCESS TO CLINICAL TRIALS, OR IS IT
	77

27

1	ACCESS TO STEM CELL THERAPIES?
2	DR. MILLAN: SO, DR. MELMED, WE BELIEVE
3	IT'S GOING TO BE ALL OF THE ABOVE. AND WE DON'T
4	HAVE THE SPECIFICS BECAUSE THIS IS STILL SOMETHING
5	THAT IS GOING OUT TO THE COMMUNITY TO DETERMINE WHAT
6	THE CURRENT LEVEL OF UNDERSTANDING IS, HOW ACTUALLY
7	THIS ALL WORKS IN THE COMMUNITY SO WE HAVE A BETTER
8	HANDLE ON THE ACADEMIC SETTINGS. LET ME JUST ALSO
9	PREFACE THIS BY SAYING THIS IS BY NO MEANS A
10	COMPREHENSIVE SLIDE THAT OUTLINES EVERY ASPECT OF
11	THE ALPHA CLINICS EXPANSION. IT ONLY HIGHLIGHTS A
12	SPECIFIC POINT IN THAT THIS WOULD BE A TRAINING
13	AN OPPORTUNITY FOR TRAINING.
14	THE ALPHA CLINICS WILL SUPPORT CLINICAL
15	TRIALS. IT WILL PROVIDE SPECIALIZED EXPERTISE FOR
16	THINGS SUCH AS THE DELIVERY AND RELEASE OF PRODUCTS,
17	PHARMACY, ALL OF THAT, BUT IT'S NOT ALL LISTED HERE.
18	IT'S IN THE STRATEGIC PLAN. THE SLIDES I CREATED
19	WERE REALLY JUST TO POINT OUT SPECIFIC TOPICS THAT
20	AROSE IN THE OCTOBER MEETING AND IT'S IN RESPONSE TO
21	THAT.
22	BUT YOUR QUESTION ABOUT COMMUNITY CARE
23	CENTERS AND ALPHA CLINICS, IN GENERAL, THE IDEA IS
24	THAT THEY WILL EACH HAVE A DIFFERENT WAY OF
25	DELIVERING THESE TYPES OF OFFERINGS, BUT BOTH WILL
	28

1	BE RELATED, BOTH WILL SERVE SOMEHOW IN SOME CAPACITY
2	AT CLINICAL TRIALS AS WELL AS HEALTHCARE DELIVERY
3	AND RESEARCH.
4	COMMUNITY CARE CENTERS OF EXCELLENCE IS
5	STILL IN ITS FORMATIVE PHASE, BUT JUST THE TYPE OF
6	RESEARCH THAT WE MIGHT BE TALKING ABOUT AT COMMUNITY
7	CARE CENTERS OF EXCELLENCE MAY BE THINGS SUCH AS
8	SOCIAL DETERMINANTS RESEARCH OR OTHER TYPES OF
9	RESEARCH THAT INFORM ACCESSIBILITY AND
10	AFFORDABILITY, THAT TYPE OF THING, OR IN ADDITION TO
11	SOCIAL DETERMINANTS, QUALITY OF LIFE, ET CETERA,
12	TYPE OF RESEARCH THAT ALSO SUPPLEMENTS AND EXPANDS
13	ON THE TYPES OF CLASSIC CLINICAL TRIAL RESEARCH THAT
14	MAY OCCUR AT THE ACADEMIC CENTERS.
15	THESE CENTERS MAY ALSO SERVE TO INFORM AND
16	DIRECT PATIENTS FROM THE COMMUNITY TO THE ACADEMIC
17	CENTERS, SO THE ALPHA CLINICS, WHEN APPROPRIATE FOR
18	BOTH INFORMATION AS WELL AS PARTICIPATION IN
19	CLINICAL TRIALS.
20	DR. MELMED: I'M NERVOUS THAT PEOPLE ARE
21	GOING TO READ THIS AND ASSUME ALL SORTS OF THINGS
22	WHICH AREN'T IN HERE. I'VE GOT A CLINIC IN FRESNO
23	WHICH HAS NO COMMUNITY CARE CENTER. CAN MY PATIENT
24	RECEIVE CELL THERAPY?
25	DR. MILLAN: SO I WANT TO SAY THAT THIS
	29
	L

1	SLIDE DECK IS ONLY FOR PURPOSES OF DISCUSSION. THE
2	STRATEGIC PLAN DOCUMENT, IT SHOULD BE THE DOCUMENT
3	THAT WE REALLY REFER TO. I DON'T KNOW IF YOU HAD A
4	CHANCE TO REVIEW. AND SO IF YOU SO IN THAT PAGE
5	IT DOESN'T TALK ABOUT SPECIFICALLY OR THOSE PAGES IT
6	DOESN'T COMMIT TO ANYTHING BECAUSE WE REALLY DON'T
7	KNOW THE FORMAT. IT'S VERY CAREFUL ABOUT THAT.
8	SO WHAT WE DO DESCRIBE IS THE INTENT
9	BEHIND THIS, WHICH IS IN SOME WAY TO ENSURE THAT WE
10	HAVE VISIBILITY TO THE OPPORTUNITIES FOR THOSE
11	TRIALS AS WELL AS, WHERE APPROPRIATE, TO HAVE
12	INVOLVEMENT OF THE COMMUNITY. BUT AFTER YOU READ
13	IT, IF YOU'RE STILL CONCERNED, PLEASE LET US KNOW.
14	DR. MELMED: THANK YOU.
15	DR. MILLAN: THANK YOU.
16	CHAIRMAN GOLDSTEIN: OKAY. PLEASE
17	PROCEED.
18	DR. MILLAN: NEXT SLIDE IS HOPEFULLY LIKE
19	THE LEAST CONTROVERSIAL BECAUSE I THINK THERE WAS
20	OVERWHELMING AGREEMENT THAT THERE IS A NEED TO
21	CREATE A SOLUTION TO MANUFACTURING AND A MORE
22	RELIABLE WAY TO TRANSFER THE TECHNOLOGY FROM OUR
23	ACADEMIC GMP EARLY PHASE PRODUCTION OUT TO
24	COMMERCIALIZATION ENTITIES. AND THIS IS THE
25	PARTNERSHIP THAT WAS DESCRIBED AT THE LAST BOARD
	30

30

1	MEETING. THE IDEA IS TO FUND ACADEMIC GMP
2	FACILITIES BOTH TO INCREASE THEIR STANDARDS OF
3	FOLLOWING QUALITY BY DESIGN, CREATING BETTER WAYS OF
4	TECH TRANSFER, AND WHERE POSSIBLE ADVANCE STANDARDS
5	THAT CAN BE SHARED ACROSS. THE IDEA IS THAT THESE
6	ACADEMIC GMP FACILITIES WOULD BOTH SUPPORT AS WELL
7	AS DEVELOP BETTER STANDARDS THAT DERISK THE EVENTUAL
8	TECH TRANSFER.
9	AND THEN IN TERMS OF HOW THE INDUSTRY
10	PARTNERS PLAY INTO THIS, CIRM WOULD FACILITATE THE
11	INTERACTION BECAUSE THESE ARE INDUSTRY PARTNERS THAT
12	ALREADY HAVE THEIR OWN BUSINESS PLAN AND MOTIVATION
13	TOWARD SUCCESS OF THESE PROGRAMS EITHER BY WAY OF
14	BEING A PROVIDER OF MANUFACTURING SERVICES,
15	RESOURCES, OR ACTUAL INVESTORS IN BRINGING THESE
16	FORWARD. SO THAT KIND OF NETWORK AND COLLABORATIVE
17	TYPE NETWORK AND PUBLIC PRIVATE PARTNERSHIP IS
18	SOMETHING THAT IS BEING DEVELOPED AS A CONCEPT
19	PROPOSAL.
20	DR. VUORI: MARIA, I HAVE A QUICK
21	QUESTION. WHAT IS THE STATUS AND HOW DOES THE IQVIA
22	CELL AND GENE THERAPY CENTER PLAY INTO ALL THIS? IS
23	IT STILL SUPPORTED BY CIRM? IS IT USED? WHAT CAN
24	YOU TELL ABOUT THAT?
25	DR. MILLAN: SO THERE WERE TWO ARMS OF
	31
	54

1	THAT WE INITIALLY CALLED IT ACCELERATING CENTER
2	AND THE TRANSLATING CENTER, AND THOSE ARE BOTH
3	AWARDED TO IQVIA. THE ACCELERATING CENTER DEALT
4	WITH REGULATORY AND CLINICAL OPERATIONS-TYPE
5	RESOURCES. THAT AWARD HAS ALREADY COMPLETED, AND
6	THERE'S A SUSTAINABLE BUSINESS UNIT WITHIN IQVIA
7	THAT STILL PROVIDES US SERVICE. AND THERE IS, I
8	BELIEVE, STILL AN OFFICE IN SAN DIEGO.
9	SO WHAT HAPPENS THERE IS THAT THEY ACHIEVE
10	THE SUPPORT OF A CERTAIN NUMBER OF PROGRAMS. IT WAS
11	A LEARNING PROCESS AND INTERACTIVE PROCESS, AND NOW
12	THEY ARE SELF-SUSTAINABLE WITHIN THEIR OWN COMPANY
13	THROUGH IQVIA, BUT NOW THEY CAN SUPPORT CELL AND
14	GENE THERAPY CLINICAL TRIALS.
15	THE TRANSLATING CENTER IS IN THE FINAL
16	STAGES OF COMPLETING, AND IT IS ACTIVELY HELPING OUR
17	PROGRAMS BOTH JUST COMPLETING THEIR PRECLINICAL
18	PROGRAMS AND MANUFACTURING AND PROCESS DEVELOPMENT
19	CONSIDERATIONS TO GET THEM PREPARED FOR CLINICAL
20	TRIALS. ONCE THAT PROGRAM ENDS, WHAT WILL HAPPEN IS
21	THEY POTENTIALLY COULD ALSO BE SOME OF THE INDUSTRY
22	PARTNERS THAT COME IN ALONG WITH OTHER INDUSTRY
23	PARTNERS TO SUPPORT CIRM PROGRAMS IN PROCESS
24	DEVELOPMENT AND MANUFACTURING, BRINGING IN THE TYPES
25	OF EXPERTISE THEY BUILT AS THEY WERE INITIALLY

32

1	SEEDED TO DO THROUGH THE INITIAL TRANSLATING CENTER
2	FUNDING.
3	DR. VUORI: GREAT. THANKS.
4	CHAIRMAN GOLDSTEIN: FOLKS, I'M VERY
5	CONSCIOUS OF THE TIME. AND I THINK WE'RE GOING TO
6	HAVE TO MOVE A LITTLE BIT FASTER IN ORDER TO MAKE IT
7	THROUGH THIS DRAFT PLAN AND THEN ALSO TO HAVE TIME
8	FOR THE BUDGET. SO I'M GOING TO ASK PEOPLE TO HOLD
9	YOUR QUESTIONS TILL THE END WHERE IT ALL POSSIBLE
10	AND TRY TO CONCENTRATE THEM AT THE LEVEL OF
11	STRATEGY, NOT AT THE LEVEL OF INDIVIDUAL DETAILS
12	ABOUT WHAT WE HAVE DONE IN THE PAST. AS WE GET TO
13	THE END, IT MAY BE A LITTLE CLEARER WHETHER WE HAVE
14	TIME OR NOT FOR SOME OF THOSE ADDITIONAL DISCUSSION
15	POINTS. I APOLOGIZE FOR THE TIME PRESSURE, BUT
16	WELCOME TO LIFE. MARIA, PLEASE.
17	DR. MILLAN: REAL LIFE AT THE TOP OF THE
18	SLIDE.
19	AND SO THANKFULLY THIS IS THE FINAL ONE,
20	BUILD A DIVERSE AND HIGHLY STRATEGIC THEME THREE,
21	BUILD A DIVERSE AND HIGHLY SKILLED WORKFORCE TO
22	SUPPORT THE GROWTH OF REGENERATIVE MEDICINE ECONOMY
23	IN CALIFORNIA. WE WILL CONNECT OUR EDUCATION PILLAR
24	PROGRAMS. AS YOU KNOW, WE HAVE VERY ROBUST
25	EDUCATION PROGRAMS THAT HAVE BEEN BROUGHT TO THE

33

1	BOARD AND AN ADDITIONAL ONE COMING UP SHORTLY. AND
2	THEN TO INTEGRATE THAT WITH ALL OF THE WORKFORCE
3	DEVELOPMENT PROGRAMS THAT WILL COME OUT OF THINGS
4	SUCH AS THE MANUFACTURING NETWORK PUBLIC PRIVATE
5	PARTNERSHIP. WE ALSO INTEND TO FOSTER ADDITIONAL
6	COLLABORATION BETWEEN COMMUNITY COLLEGES,
7	UNIVERSITIES, AND OTHER ACADEMIC ENTITIES FOR
8	EFFORTS THAT WE TALKED ABOUT PREVIOUSLY, SUCH AS
9	OVERCOMING THE WORKFORCE DEVELOPMENT NEEDS FOR
10	MANUFACTURING AS WELL AS BUILDING EXPERTISE IN
11	PROCESS DEVELOPMENT SCIENCES.
12	AND WE WILL LEVERAGE ALPHA CLINICS AND
13	COMMUNITY CARE CENTERS, HEALTHCARE DELIVERY SYSTEMS
14	TO DEVELOP EDUCATION CURRICULA. THIS SOMETHING THAT
15	DR. MIASKOWSKI MENTIONED EARLIER ABOUT ARE WE
16	INVOLVED WILL WE BE INVOLVED IN CURRICULUM
17	DEVELOPMENT? WE BELIEVE OUR EDUCATION PROGRAMS AS
18	WELL AS ALL THESE OTHER INFRASTRUCTURE PROGRAMS BY
19	NATURE WILL BE ABLE TO BUILD CURRICULA AS WELL AS
20	POTENTIAL CERTIFICATION PROGRAMS.
21	ALL RIGHT. I JUST LOST MY SLIDES AGAIN.
22	I THINK THAT'S IT. DR. GOLDSTEIN.
23	CHAIRMAN GOLDSTEIN: WE'RE CLOSER TO THE
24	END THAN I THOUGHT. SO WE DO HAVE TIME FOR SOME
25	DETAILS AS WELL AS STRATEGIC QUESTIONS. PLEASE,
	34

1	MEMBERS OF THE SUBCOMMITTEE. MARK FISCHER-COLBRIE,
2	TAKE IT AWAY.
3	DR. FISCHER-COLBRIE: THIS IS AN
4	ADDITIONAL DATA POINT. I THINK FROM A STRATEGIC
5	PERSPECTIVE, WE SHOULD DO A LITTLE BIT OF A CALL-OUT
6	AROUND DATA SCIENCE; IN OTHER WORDS, USING
7	ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING TOOLS
8	TO HELP ACCELERATE SCIENCE. I THINK IN THE DOCUMENT
9	WE MAKE A VERY OBLIQUE REFERENCE TO AI, AND I THINK
10	THAT'S GOING TO BE AN IMPORTANT STRATEGIC ELEMENT
11	FOR US TO EXPLORE. AND I THINK SUPPORTING THAT IS
12	THE CONCEPT OF THE FAIR DATA STANDARDS, WHICH GETS
13	TO OUR DATA SHARING ASPECT AS WELL. AND THOSE FAIR
14	DATA STANDARDS THAT HELP SUPPORT MACHINE LEARNING
15	AND DATA SCIENCE EXPANSION AND ACCELERATION, THAT'S
16	FINDABLE, ACCESSIBLE, INTEROPERABLE, AND REUSABLE.
17	WE SORT OF TOUCHED A LITTLE BIT ON THE
18	DATA SIDE INTEROPERABLE, BUT I WOULD RECOMMEND
19	SOMEWHERE WE BAKE IN THAT WE HAVE A GOAL OF TRYING
20	TO GET TO THE FAIR DATA STANDARDS, WHICH IS AN
21	ACKNOWLEDGED DATA STREAM FOR BEING ABLE TO SHARE
22	INFORMATION IN A BROADER MANNER.
23	DR. MILLAN: THANK YOU SO MUCH. IT'S
24	ACTUALLY WE WILL MAKE SURE THAT IT'S MORE
25	APPARENT, BUT THE IDEA BEHIND THE KNOWLEDGE NETWORKS
	35

1	IS JUST THAT. THOSE ARE KIND OF THE HOW-TOS AND THE
2	LOGISTICS OF THAT.
3	JUST BY THE WAY, IN OUR PROGRAM
4	ANNOUNCEMENTS ALREADY, OUR RFA'S, WHEN WE ASK FOR
5	APPLICANTS TO SUBMIT THEIR SHARING PLAN, WE DO
6	SPECIFICALLY POINT TO THE FAIR DATA STANDARDS AS ONE
7	OF THE REFERENCES.
8	IN ADDITION, DATA SCIENCE IS SOMETHING
9	THAT'S INCLUDED IN OUR EDUCATION PROGRAMS AND WILL
10	BE EVEN MORE SOMETHING YOU WILL SEE A LITTLE BIT
11	MORE DRAMATICALLY IN THE UNDERGRADUATE EDUCATION
12	PROGRAM WHICH WILL BE COMING TO YOU SOON. BUT TO
13	YOUR POINT, WE SHOULD HIGHLIGHT IT AS ONE OF THE
14	AREAS WITHIN THE EDUCATION PROGRAMS THAT WILL BE
15	SPECIFICALLY INCLUDED. SO WE WILL INCLUDE THAT IN
16	THE WORDING. THANK YOU SO MUCH.
17	DR. FISCHER-COLBRIE: THANK YOU.
18	CHAIRMAN GOLDSTEIN: OTHER QUESTIONS,
19	COMMENTS, OR SUGGESTIONS PLEASE.
20	DR. MELMED: MARIA, IN AN EARLIER
21	ITERATION TWO OR THREE YEARS AGO OF THIS PLAN WHEN
22	WE FIRST STARTED TALKING ABOUT IT, WE DISCUSSED THE
23	POSSIBILITY OF CIRM BECOMING AN ACCREDITING AGENCY
24	FOR CLINICAL TRAINING IN CELL THERAPY. DID THAT
25	FALL OFF THE RADAR SCREEN? WAS THERE A LACK OF

INTEREST, OR IS IT NOT --1 DR. MILLAN: OH, THERE IS DEFINITELY A 2 VERY STRONG INTEREST. AND WHAT WE'RE HOPING IS THAT 3 WE ARE ENCOURAGING OUR ALPHA CLINICS EXPANSION 4 APPLICANTS TO BE ABLE TO INCLUDE THAT IN THEIR 5 6 PLANS. DR. MELMED: THAT WOULD HAVE TO COME FROM 7 US, NOT FROM THE CLINIC. IF WE'RE GOING TO BECOME 8 9 AN AGENCY WHICH IS GOING TO ACCREDIT TRAINING PROGRAMS IN CLINICAL CELL THERAPY, THAT WOULD HAVE 10 TO BE A CENTRAL CIRM PROJECT, NOT --11 12 DR. MILLAN: SURE. I DO BELIEVE, NOT JUST FOR CLINICAL, BUT OTHER TYPE AREAS AS WELL THAT ONCE 13 14 WE -- CIRM ITSELF, THOUGH, IS NOT THE EXPERT IN TRAINING. WE DON'T RUN FELLOWSHIP PROGRAMS. 15 WE DON'T DO ANY OF THAT. SO WE REALLY WILL RELY ON OUR 16 17 ACADEMIC CENTERS TO SAY HERE'S A CURRICULA, HERE'S A TRAINING, HERE'S THE REQUIREMENTS, AND ON TOP OF 18 19 THAT, THERE ARE THESE STEM CELL-RELATED THINGS. WE 20 PROPOSE TO YOU THAT THIS MAKES UP -- AND IT WILL BE UP TO CIRM TO DECIDE THAT MEETS OUR STANDARDS, AND 21 22 THEN WE WOULD BRING IT TO THE BOARD AS TO WHETHER WE CAN HAVE -- WHETHER WE CAN ACTUALLY HAVE IT AS CIRM 23 24 CERTIFIED TRAINING PROGRAM. 25 AND THAT'S SOMETHING THAT WE DEFINITELY 37

1	HAVE DISCUSSED. IT HAS NOT FALLEN OFF OUR RADAR.
2	BUT IN TERMS OF THE HOW-TOS, IT REALLY NEEDS TO GROW
3	FROM THE ACADEMIC CENTERS TO FEED INTO THAT
4	BECAUSE AND SO I MENTIONED THE ALPHA CLINICS
5	EXPANSION BECAUSE THAT'S THE VERY PLACE WHERE
6	CLINICAL RESEARCH OCCURS. THAT'S A STARTING POINT.
7	AND THEN FROM THAT WE CAN BUILD ON HOW WE BRING IN
8	ADDITIONAL CENTERS AND HOW WE INTERACT WITH
9	ACCREDITING BODIES AND SOCIETIES.
10	CHAIRMAN GOLDSTEIN: IF I CAN ADD A
11	COMMENT HERE. IT SEEMS TO ME THAT A RELEVANT
12	COMPARISON WOULD BE THE NIH IN THIS CASE. SO THE
13	NIH ITSELF DOESN'T REALLY DO A LOT OF ACCREDITATION
14	PROGRAMS; BUT, OF COURSE, IT FUNDS A GREAT DEAL OF
15	RESEARCH AND PROFESSIONAL ACTIVITIES AND CURRICULUM
16	DEVELOPMENT AND ALL THAT. THAT'S PROBABLY WHERE
17	THOSE SORTS OF ACCREDITATIONS SHOULD ORIGINATE FOR
18	US AS WELL. BECAUSE I THINK YOU'RE RIGHT, MARIA.
19	TO BUILD OUT AN ACCREDITATION UNIT WITHIN CIRM, THAT
20	IS A SERIOUS UNDERTAKING. AND GIVEN THE LIMITS ON
21	AMOUNT OF FINANCIAL EXPENDITURE AND NUMBER OF
22	EMPLOYEES, THIS MAY NOT BE THE BEST PLACE FOR US TO
23	BUILD IT OUT. BUT OTHER COMMENTS PLEASE. WELL,
24	THAT KILLED DISCUSSION.
25	DR. MILLAN: BUT HAVING SAID THAT, THOUGH,
	38

1	I REALLY DO THINK THAT WE HAVE AN OPPORTUNITY TO
2	INFLUENCE IN A WAY THAT WOULD MAKE THAT SO. AND SO
3	I DON'T THINK I THINK WITHOUT HAVING TO DO A
4	LAYOUT IN TERMS OF OUR OWN INFRASTRUCTURE, OUR OWN
5	FUNDS, I THINK JUST BY VIRTUE OF PROMOTING THESE
6	STANDARDS AND PROMOTING THESE OPPORTUNITIES WITHIN
7	OUR PROGRAMS IN A STRUCTURED AND ORGANIZED WAY,
8	THERE ARE I THINK THAT THE LEADERS WITHIN THE
9	ACADEMIC CENTERS ARE VERY INTERESTED IN KIND OF
10	BEING THE AMBASSADORS TO MAKE THAT HAPPEN. THAT'S
11	WHERE IT BELONGS. IT BELONGS WITH THE ACADEMIC
12	LEADERS, WITH THOSE WHO RUN FELLOWSHIP PROGRAMS, OR
13	INTEGRATED WITHIN THE UNIVERSITIES THAT DO
14	APPOINTMENTS.
15	CHAIRMAN GOLDSTEIN: DR. MELMED, YOU
16	SATISFIED WITH THAT?
17	DR. MELMED: YEAH. I HOPE THAT SOMEONE
18	ELSE DOESN'T DO IT INSTEAD OF US. CAN YOU IMAGINE
19	THE CARDIOLOGISTS SUDDENLY SAYING, WE GOT A STEM
20	CELL PROGRAM IN CARDIOLOGY? YEAH. IT HAS TO BE
21	LEADERS.
22	DR. MILLAN: I THINK WE SHOULD DO IT WITH
23	THE CARDIOLOGISTS.
24	DR. VUORI: SORRY. MAYBE CONVERSATION
25	WITH CALIFORNIA MEDICAL ASSOCIATION IF THEY HAVE
	39

1	ANY
2	DR. MELMED: THEY DON'T DO IT, NO.
3	DR. VUORI: THEY DON'T WANT TO DO THAT.
4	DR. MELMED: THEY'LL GO TO THE
5	PROFESSIONAL SOCIETIES.
6	DR. MILLAN: PROFESSIONAL SOCIETIES. I
7	ALWAYS POINT TO A STORY WHERE WHEN I STARTED MY
8	TRANSPLANT SURGERY TRAINING, THERE WAS NO SPECIFIC
9	CERTIFICATION. YOU WERE A GENERAL SURGEON AND YOU
10	WENT THROUGH TRAINING, YOU DID AS MANY CASES AND YOU
11	GOT THE REQUIRED AMOUNT, AND THEN YOU WERE ABLE TO
12	GET A JOB AS A TRANSPLANT SURGEON. BUT THEN DURING
13	MY TRAINING AT THE VERY END, THE AMERICAN SOCIETY
14	FOR TRANSPLANT SURGEONS THEN CREATED REQUIREMENTS,
15	AND THEN PROGRAMS WERE THEN DEEMED ABLE TO GIVE
16	CERTIFICATION FOR TRANSPLANT SURGERY.
17	SO IT'S SOMETHING THAT REALLY DOES HAPPEN
18	AS THE FIELD MATURES, AND I THINK CIRM CAN PLAY AN
19	IMPORTANT PART IN MATURING THAT DIRECTION.
20	CHAIRMAN GOLDSTEIN: GOOD.
21	DR. MELMED: THANK YOU.
22	CHAIRMAN THOMAS: OTHER QUESTIONS OR ITEMS
23	OF DISCUSSION?
24	DR. LEVITT: SO THEME ONE HAS A LOT OF
25	REFERENCE TO SHARED RESEARCH LABORATORIES AND
	40

1	DEVELOPMENT OF HUBS. AND SOMETIMES THE STATEMENTS
2	ARE VERY EXPLICIT ABOUT WHAT THE GOALS ARE, WHICH IS
3	WHAT A STRATEGIC PLAN SHOULD DO, BUT SOMETIMES IT
4	LACKS SPECIFICITY. LIKE I STILL DON'T QUITE
5	UNDERSTAND WHAT A RESEARCH HUB WILL BE AND WHO WILL
6	HAVE ACCESS TO IT. AND I UNDERSTAND THE LIMITATIONS
7	OF WHAT YOU INCLUDE IN THE OVERARCHING STRATEGIC
8	PLAN, BUT SOME OF THIS REQUIRES A LOT OF
9	SPECIFICITY.
10	I GO ONTO THE CIRM WEBSITE, AND I DON'T
11	FIND VERY MUCH INFORMATION ABOUT SHARED RESEARCH
12	LABORATORIES, FOR EXAMPLE. I DON'T WANT TO SEE A
13	REPEAT OF THAT, WHERE IT SEEMS VERY INSULAR. THAT
14	IS, THEY EXIST, BUT IT'S VERY INSULAR IN TERMS OF
15	BECAUSE HERE THERE'S LANGUAGE ABOUT ACCESS TO THESE
16	HUBS OUTSIDE OF THE FUNDED INSTITUTIONS THAT I
17	ASSUME ALSO SCIENTISTS WHO ARE DOING STEM CELL
18	REGENERATIVE MEDICINE RESEARCH WHO MAY NOT BE
19	RUNNING THE HUB NONETHELESS NEED ACCESS TO IT IF
20	THESE ARE GOING TO BE TRULY SHARED.
21	SO I'M JUST SPEAKING OF SOMEBODY I'M
22	OUTSIDE OF THE COMMUNITY AND LOOK TOWARDS IT, AND I
23	DON'T SEE AS MUCH CLARITY AS I THINK THERE SHOULD
24	BE. FOR EXAMPLE, THERE'S A STATEMENT IN THERE THAT
25	SAYS SOME COMPETENCY HUBS COULD SERVE AS A WORKFORCE
	41

1	TRAINING MICROCOSM. I THINK THAT'S A GREAT IDEA,
2	BUT COULD IS LIKE, WELL, WILL IT BE, OR IS THIS PART
3	OF THE STRATEGIC PLAN OR THIS IS AN OPTION. SO I
4	THINK A STRATEGIC PLAN NEEDS IN SOME PLACES A BIT
5	MORE SPECIFICITY. WILL BE. OKAY. IT WILL BE.
6	THAT MEANS THE STRATEGIC PLAN.
7	CHAIRMAN GOLDSTEIN: DR. LEVITT, COULD YOU
8	PLEASE SUPPLY PRESIDENT MILLAN WITH SOME OF THOSE
9	COMMENTS IN WRITING SO SHE KNOWS WHERE YOUR CONCERNS
10	ARE? MARIA, THAT GOING TO BE OKAY WITH YOU?
11	DR. LEVITT: ABSOLUTELY.
12	DR. MILLAN: YES, BUT I THINK THAT I
13	THINK I KNOW WHERE THAT COMES FROM IN TERMS OF THE
14	IDEA THAT SOME OF IT LACKS SPECIFICITY. THE IDEA OF
15	COMPETENCY HUBS IS A VERY BROAD DESCRIPTION THAT
16	REALLY SPEAKS TO A PRINCIPLE RATHER THAN AN ACTUAL
17	PROGRAM. WHEREAS, A SHARED LAB, LIKE A CELL-BASED
18	SHARED LAB LIKE IPSC'S OR WHATEVER, ARE SPECIFIC.
19	OKAY. WE JUST NEED TO DO A BETTER JOB OF THIS.
20	THE SHARED LABS IS AN EXAMPLE OF A
21	COMPETENCY HUB. WHEREAS, A COMPETENCY HUB COULD BE
22	SOMETHING THAT'S NOT NECESSARILY SPECIFICALLY AND
23	PRIMARILY CIRM FUNDED, BUT IT COULD BE SOMETHING
24	THAT'S BUILT INTO THE THINGS WE DO, SUCH AS IT COULD
25	BE THAT THE ALPHA CLINICS, THE CLINICAL NETWORKS,

_	
1	HAVE A VERY SPECIALIZED IMAGING CORE THAT BECOMES A
2	COMPETENCY HUB. THEN THAT IS SOMETHING THAT HAS
3	BROAD APPLICATION ACROSS THE ALPHA CLINICS NETWORK.
4	WHEREAS, THE SHARED LABS ITSELF FOR WHICH THERE'S
5	SPECIFIC FUNDING WITH POTENTIAL RENOVATION FUNDING,
6	WE ENVISION AS THE FIRST ROLLOUT AN EXAMPLE OF A
7	COMPETENCY HUB WILL BE SOMETHING THAT PROVIDES FOR
8	AND DEALS WITH SPECIALIZED CELLS AND CELL MODELS.
9	SO WE WILL TAKE A LOOK AT THAT SO THAT WE
10	CAN MAKE IT VERY CLEAR WHAT IS THE BROAD PRINCIPLE,
11	AND THEN THIS IS AN EXAMPLE OF IT AS A SPECIFIC
12	PROGRAM.
13	DR. LEVITT: I THINK THAT WOULD BE REALLY
14	HELPFUL.
15	DR. MILLAN: THANK YOU VERY MUCH.
16	CHAIRMAN GOLDSTEIN: OKAY. ADDITIONAL
17	QUESTIONS OR DISCUSSION BEFORE WE WRAP THIS UP?
18	OKAY. CAN WE GET A MOTION ON THE TABLE PLEASE? I
19	THINK, MARIA
20	DR. FISCHER-COLBRIE: I MOVE TO APPROVE.
21	CHAIRMAN GOLDSTEIN: HERE WE GO. THANK
22	YOU.
23	DR. MILLAN: I'M SORRY. I FORGOT TO ASK
24	FOR THAT.
25	CHAIRMAN GOLDSTEIN: THAT'S MY JOB TO ASK.
	43

1	DR. LEVITT: SECOND.
2	MS. BONNEVILLE: WAS THAT PAT?
3	DR. LEVITT: YEAH.
4	MS. BONNEVILLE: THANK YOU.
5	CHAIRMAN GOLDSTEIN: OKAY. FURTHER
6	DISCUSSION BEFORE WE MOVE ON? ANY ADDITIONAL FINAL
7	QUESTIONS, FINAL DISCUSSION? HEARING NONE, MEMBERS
8	OF THE PUBLIC, PUBLIC COMMENTS? MARIA, WE GOT ANY?
9	MS. BONNEVILLE: NO, NO HANDS RAISED.
10	CHAIRMAN GOLDSTEIN: OKAY. THEN TO THE
11	EXCITING PART. MARIA, COULD YOU PLEASE CALL THE
12	ROLL.
13	MS. BONNEVILLE: HAIFA ABDULHAQ.
14	DR. ABDULHAQ: PRESENT.
15	MS. BONNEVILLE: ELENA FLOWERS.
16	DR. FLOWERS: PRESENT.
17	CHAIRMAN GOLDSTEIN: I THINK WE NEED A YES
18	OR A NO.
19	MS. BONNEVILLE: THIS IS A YES-OR-NO VOTE.
20	MR. TORRES: RIGHT. NOT A ROLL CALL.
21	YOU NEED TO START THE ROLL CALL AGAIN, MARIA.
22	MS. BONNEVILLE: I'M DOING SO. HAIFA.
23	DR. ABDULHAQ: YES.
24	MS. BONNEVILLE: THANK YOU. ELENA
25	FLOWERS.
	44

1		DR. FLOWERS: YES.
2		MS. BONNEVILLE: MARK FISCHER-COLBRIE.
3		DR. FISCHER-COLBRIE: AYE.
4		MS. BONNEVILLE: JUDY GASSON.
5		DR. GASSON: YES.
6		MS. BONNEVILLE: LARRY GOLDSTEIN.
7		CHAIRMAN GOLDSTEIN: YES.
8		MS. BONNEVILLE: DAVID HIGGINS. PAT
9	LEVITT.	
10		DR. LEVITT: YES.
11		MS. BONNEVILLE: DAVID LO.
12		DR. LO: YES.
13		MS. BONNEVILLE: DAVID MARTIN.
14		DR. MARTIN: YES.
15		MS. BONNEVILLE: SHLOMO MELMED.
16		DR. MELMED: YES.
17		MS. BONNEVILLE: CHRISTINE MIASKOWSKI.
18		DR. MIASKOWSKI: YES.
19		MS. BONNEVILLE: JONATHAN THOMAS.
20		CHAIRMAN THOMAS: YES.
21		MS. BONNEVILLE: ART TORRES.
22		MR. TORRES: YES.
23		MS. BONNEVILLE: KRISTINA VUORI.
24		DR. VUORI: YES.
25		MS. BONNEVILLE: KAROL WATSON. KEITH
		45
		-TJ

1	ΥΑΜΑΜΟΤΟ.
2	DR. YAMAMOTO: YES.
3	MS. BONNEVILLE: MOTION CARRIES.
4	CHAIRMAN GOLDSTEIN: OKAY. VERY GOOD.
5	THANK YOU, MEMBERS OF THE COMMITTEE.
6	OKAY. FINAL ITEM ON TODAY'S MEETING,
7	CONSIDERATION OF A REVISED CIRM BUDGET FOR FISCAL
8	YEAR 21/22. IS THAT POUNEH SIMPSON.
9	MS. SIMPSON: YES. GOOD AFTERNOON.
10	CHAIRMAN GOLDSTEIN: HANG ON A SECOND.
11	MARK, YOU HAVE YOUR HAND UP.
12	DR. FISCHER-COLBRIE: JUST A QUICK
13	COMMENT, THAT I'D LIKE TO PUBLICLY ACKNOWLEDGE THE
14	TREMENDOUS WORK BY THE CIRM STAFF TO PREPARE THE
15	STRAT PLAN IN CONJUNCTION WITH ALL THE PARTIES THAT
16	THEY INTERACTED WITH, BUT EXTREMELY WELL DONE. SO
17	THANK YOU.
18	CHAIRMAN GOLDSTEIN: THANK YOU VERY MUCH
19	FOR THAT. YES, PRESIDENT MILLAN, COMPLIMENT YOUR
20	STAFF, EVERYBODY HERE. GOOD JOB.
21	DR. MILLAN: I WANT TO THANK I MEAN THE
22	TEAM WORKED ON THIS, AND THE LEADERSHIP TEAM HAD
23	ORGANIZED ALL THE DIFFERENT WORKS GROUPS AS YOU SAW
24	FROM HOW IT WAS DESCRIBED IN THE END. AND THE
25	WRITING TEAM, WHICH INCLUDES SHYAM PATEL AND MITRA
	46

1	HOOSHMAND AND MARIA BONNEVILLE IN TERMS OF KIND OF
2	THE LOOK AND FEEL OF THE DOCUMENT ITSELF, THEY WERE
3	INSTRUMENTAL IN KIND OF THE FINAL PRODUCT. SO
4	REALLY THIS IS A HUGE TEAM EFFORT INVOLVING THE
5	ENTIRE ORGANIZATION, THE BOARD, AND OUR EXTERNAL
6	STAKEHOLDERS. THANK YOU VERY MUCH.
7	CHAIRMAN GOLDSTEIN: GREAT. WAY TO LEAD
8	THE TEAM, MARIA. OKAY.
9	NOW ON TO POUNEH. GREAT. THANK YOU.
10	MS. SIMPSON: YES. THANK YOU FOR THE
11	OPPORTUNITY TO PRESENT TO YOU. I'M POUNEH SIMPSON,
12	THE DIRECTOR OF FINANCE. I'LL BE PRESENTING THE
13	MID-YEAR REVISED BUDGET PROPOSALS TO YOU FOR
14	APPROVAL.
15	SO JUST TO GIVE YOU SOME CONTEXT WITH
16	REGARDS TO THE MID-YEAR PROPOSAL, IN 2021 WHEN THE
17	BOND PASSED, WE CAME TO YOU WITH A MID-YEAR BUDGET
18	TO REFLECT THE RAMPING UP OF CIRM BECAUSE THE
19	ORIGINAL BUDGET WAS BASED ON A RAMPING DOWN.
20	SIMILAR TO LAST YEAR, WE ARE COMING TO YOU
21	WITH A MID-YEAR BUDGET BASED ON WHAT YOU APPROVED IN
22	JUNE AND THEN THE CHANGES THAT NEED TO OCCUR TO
23	REFLECT THE INITIATIVES THAT DR. MILLAN JUST
24	PRESENTED AS PART OF THE STRATEGIC PLAN.
25	SO AS BACKGROUND, IN JUNE THE BOARD
	47

1	APPROVED A BUDGET OF 360 MILLION IN RESEARCH GRANTS.
2	AND THIS SLIDE KIND OF SUMMARIZES THE DIFFERENT
3	CATEGORIES AND THE AMOUNTS THAT WERE APPROVED IN
4	JUNE.
5	SO CONTINUING ON WITH WHAT THE PROPOSAL IS
6	THIS YEAR, WE ARE COMING TO YOU WITH A REQUEST OF
7	\$114 MILLION IN INCREASES. SO THE MIDDLE COLUMN
8	REPRESENTS THE MID-YEAR BUDGET IN TWO CATEGORIES.
9	THE FIRST CATEGORY, THE TRANSLATIONAL RESEARCH
10	BUDGET, WE'D LIKE TO INCREASE BY 34 MILLION BECAUSE
11	THE ORIGINAL BUDGET THAT WAS APPROVED WAS BASED ON
12	BENCHMARK COSTS OF PRIOR FUNDING ROUNDS. SINCE THE
13	BEGINNING OF THIS YEAR, WE HAVE HAD AN INCREASED
14	TREND IN GRANT REQUESTS AND VIABLE CANDIDATES, SO WE
15	ARE ASKING FOR AN INCREASE TO BE ABLE TO FULLY FUND
16	THE REQUESTS THIS YEAR.
17	AND THEN WITH THE INFRASTRUCTURE, WE WOULD
18	LIKE TO SUPPORT PROGRAMS ANTICIPATED IN 20/21 THAT
19	DR. MILLAN JUST MENTIONED IN THE STRATEGIC PLAN FOR
20	AN INCREASED TOTAL OF 114 MILLION OR A TOTAL BUDGET
21	OF 447 MILLION. SO WE'D ASK FOR YOUR SUPPORT AND
22	APPROVAL FOR THAT REQUEST. THAT IS THE
23	PRESENTATION, AND I'M HAPPY TO ANSWER ANY QUESTIONS
24	YOU MAY HAVE.
25	CHAIRMAN GOLDSTEIN: MAYBE I'LL ASK THE
	48

1	FIRST ONE. SO IF YOU RATCHET THIS FORWARD TEN
2	YEARS, ARE WE STILL IN GOOD SHAPE?
3	MS. SIMPSON: YES, ABSOLUTELY. WE HAVE
4	TAKEN INTO CONSIDERATION FUNDING OF THE CORE
5	PILLARS, AND THERE'S FUNDING FOR AT LEAST TEN YEARS
6	AND DEFINITELY MORE DEPENDING ON HOW MUCH THE AWARDS
7	ARE EACH YEAR.
8	CHAIRMAN GOLDSTEIN: AND THEN A REQUEST.
9	IF WE'RE GOING TO KEEP THE SLIDES UP, COULD YOU KEEP
10	THE SLIDE UP WITH THE PROPOSED BUDGET CHANGE? THANK
11	YOU. MEMBERS OF THE COMMITTEE.
12	DR. VUORI: I HAVE A VERY SIMILAR QUESTION
13	TO LARRY. CAN YOU REMIND IF ANY OF THESE CATEGORIES
14	WERE CAPPED IN THE PROP 14?
15	MS. SIMPSON: I WILL DEFER TO OUR GRANTS
16	MANAGEMENT TEAM FOR THAT.
17	DR. MILLAN: I CAN SPEAK TO THAT, POUNEH.
18	SO, DR. VUORI, THERE WERE NO CAPS TO SPECIFIC
19	PROGRAMS. THERE'S A CAP ON ANNUAL EXPENDITURE FOR
20	RESEARCH, AND THESE WERE ALL WITHIN THAT CAP. THE
21	ACTUAL PROPOSED BUDGET IN JUNE THAT WAS PRESENTED BY
22	JENNIFER LEWIS WAS BASED ON BENCHMARKING FOR WHAT
23	OUR PAST PERFORMANCE HAD BEEN FOR THE DIFFERENT
24	CATEGORIES BASED ON THE YIELD FOR EACH REVIEW, THE
25	AMOUNT, THE AVERAGE AMOUNT PER EACH AWARD, AND THE

49

1	NUMBER OF CYCLES OF ANTICIPATED AWARDS. AND THAT'S
2	HOW WE ARRIVED AT THE NUMBERS.
3	AND THE REASON THAT WE INCREASED THE
4	TRANSLATIONAL IS BECAUSE THE PERFORMANCE THIS YEAR
5	WAS HIGHER THAN OUR PRIOR BENCHMARK. WE ALWAYS
6	BENCHMARK TO THE MAXIMUM YIELD JUST TO MAKE SURE
7	THAT WE HAVE ENOUGH FUNDS AVAILABLE FOR THOSE THAT
8	ARE RECOMMENDED TO THE BOARD.
9	DR. VUORI: THANKS.
10	CHAIRMAN GOLDSTEIN: MARK FISCHER-COLBRIE
11	PLEASE. I THINK YOU ARE ON MUTE.
12	DR. FISCHER-COLBRIE: SORRY. DO WE HAVE A
13	GOOD TRACKING MECHANISM FOR TRACKING THE \$1.5
14	BILLION INITIATIVE RELATED TO BRAIN TREATMENTS?
15	DR. MILLAN: THAT'S BEING TRACKED ACTIVELY
16	BY OUR SCIENCE AND GRANTS MANAGEMENT TEAM.
17	DR. FISCHER-COLBRIE: THANK YOU.
18	CHAIRMAN GOLDSTEIN: THANK YOU. OTHER
19	QUESTIONS, CONCERNS, WHAT HAVE YOU FROM THE
20	SUBCOMMITTEE?
21	CHAIRMAN THOMAS: LARRY, CAN I JUST MAKE
22	ONE QUICK COMMENT. JUST FOR MEMBERS OF THE
23	SUBCOMMITTEE, THESE NUMBERS WERE PREVIEWED WITH AL
24	ROWLETT, AS CHAIR OF THE FINANCE SUBCOMMITTEE, AND
25	MYSELF LAST WEEK, AND WE ARE COMPLETELY ALIGNED WITH
	50

1	THESE AS THE NUMBERS THAT SHOULD GO FORWARD.
2	CHAIRMAN GOLDSTEIN: GOOD. THANK YOU,
3	J.T. OTHER QUESTIONS OR COMMENTS?
4	MR. TORRES: MOVE TO APPROVE.
5	DR. VUORI: SECOND.
6	MS. BONNEVILLE: ART AND KRISTINA; IS THAT
7	CORRECT?
8	DR. VUORI: YES.
9	CHAIRMAN GOLDSTEIN: THANK YOU. MOTION IS
10	ON THE TABLE. ANY FURTHER QUESTIONS, MEMBERS OF THE
11	SUBCOMMITTEE? HEARING NONE, ANY QUESTIONS OR
12	CONCERNS OR COMMENTS FROM THE PUBLIC? NOTHING,
13	MARIA?
14	MS. BONNEVILLE: NO.
15	CHAIRMAN GOLDSTEIN: ENGAGED AS ALWAYS.
16	LET'S SEE. I GUESS WE'RE UP TO CALLING THE ROLL.
17	MARIA.
18	MS. BONNEVILLE: HAIFA ABDULHAQ.
19	DR. ABDULHAQ: YES.
20	MS. BONNEVILLE: ELENA FLOWERS.
21	DR. FLOWERS: YES.
22	MS. BONNEVILLE: MARK FISCHER-COLBRIE.
23	DR. FISCHER-COLBRIE: AYE.
24	MS. BONNEVILLE: JUDY GASSON.
25	DR. GASSON: YES.
	51
	JL

	•
1	MS. BONNEVILLE: LARRY GOLDSTEIN.
2	CHAIRMAN GOLDSTEIN: YES.
3	MS. BONNEVILLE: DAVID HIGGINS. PAT
4	LEVITT.
5	DR. LEVITT: YES.
6	MS. BONNEVILLE: DAVID LO.
7	DR. LO: YES.
8	MS. BONNEVILLE: DAVID MARTIN.
9	DR. MARTIN: YES.
10	MS. BONNEVILLE: SHLOMO MELMED.
11	DR. MELMED: YES.
12	MS. BONNEVILLE: CHRISTINE MIASKOWSKI.
13	DR. MIASKOWSKI: YES.
14	MS. BONNEVILLE: JONATHAN THOMAS.
15	CHAIRMAN THOMAS: YES.
16	MS. BONNEVILLE: ART TORRES.
17	MR. TORRES: AYE.
18	MS. BONNEVILLE: KRISTINA VUORI.
19	DR. VUORI: YES.
20	MS. BONNEVILLE: KAROL WATSON. KEITH
21	YAMAMOTO.
22	DR. YAMAMOTO: YES.
23	MS. BONNEVILLE: THE MOTION CARRIES.
24	CHAIRMAN GOLDSTEIN: GREAT. ANY FINAL
25	QUESTIONS OR ISSUES FROM THE SUBCOMMITTEE BEFORE WE
	52
	JL

1	MOVE TOWARDS ADJOURNMENT? HEARING NONE, MARIA, ANY
2	FINAL PUBLIC COMMENT, QUESTIONS, WHAT HAVE YOU? NO.
3	THAT'S GOOD. LET'S SEE. DO WE HAVE TO HAVE A
4	MOTION TO ADJOURN A MEETING, OR CAN I JUST ADJOURN
5	US?
6	MS. BONNEVILLE: YOU CAN JUST ADJOURN.
7	CHAIRMAN GOLDSTEIN: OKAY. NOBODY IS
8	GOING TO COMPLAIN ABOUT A MEETING ENDING EARLY. SO
9	LET'S DO IT.
10	MR. TORRES: GOOD JOB, MR. CHAIRMAN.
11	CHAIRMAN THOMAS: THANK YOU, LARRY.
12	MS. BONNEVILLE: THANK YOU, EVERYONE. SEE
13	YOU AT THE BOARD MEETING.
14	(THE MEETING WAS THEN CONCLUDED AT 2:09 P.M.)
15	
16	
17	
18	
19	
20	
21	
22	
23	
24	
25	
	53
	122 HENNA COUDT SANDDOINT IDAHO 92964

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 ZOOM PROCEEDINGS BEFORE THE SCIENCE SUBCOMMITTEE OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON NOVEMBER 29, 2021, 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 133 HENNA COURT SANDPOINT, IDAHO (208) 290-3543

54