## BEFORE THE INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE TO THE

# CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE ORGANIZED PURSUANT TO THE CALIFORNIA STEM CELL RESEARCH AND CURES ACT

#### SPECIAL MEETING

LOCATION: AS INDICATED ON THE AGENDA

MAY 12, 2009 7:30 A.M. DATE:

BETH C. DRAIN, CSR REPORTER:

CSR. NO. 7152

BRS FILE NO.: 84511

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TUESDAY, MAY 12, 2009; 7:30 A.M.
MS. KING: WHY DON'T WE, BEFORE WE TAKE A
ROLL CALL, JUST START WITH DR. LOMAX LEADING US
THROUGH THE DOCUMENT, ITEM NO. 3.
DR. LOMAX: THANK YOU, MELISSA. GOOD
MORNING, EVERYONE. THE DOCUMENT WE POSTED
YESTERDAY, WHICH YOU ALL RECEIVED YESTERDAY
AFTERNOON, IS OUR LATEST REVISION OF THE COMMENTS
WHICH WE HAVE PROPOSED TO SUBMIT TO NIH. AND WE'VE
TRIED TO OUTLINE A SET OF COMMENTS WHICH WE BELIEVE
IS REFLECTIVE OF NOT JUST SORT OF INTERNAL
DELIBERATIONS HERE, BUT AN EMERGING CONSENSUS REALLY
NATIONALLY AROUND THE SORT OF TYPE OF OVERSIGHT AND
REVIEW MECHANISMS WHICH SHOULD GUIDE THE UTILIZATION
OF HUMAN EMBRYONIC STEM CELL LINES IN STEM CELL
RESEARCH.
SO, AGAIN, I THINK THE POINT IS THAT THIS
IS SORT OF A CONSENSUS APPROACH AMONG LEADING
RESEARCH INSTITUTIONS, STATES THAT HAVE FUNDED STEM
CELL RESEARCH. AND
(OPERATOR JOINS ROBERT KLEIN AND JOAN
SAMUELSON.)
MR. TORRES: THANK YOU FOR BEING HERE.
GEOFF IS GOING OVER HIS RESPONSE TO NIH, BOB, AND
3

1	THEN WE'LL GET BACK TO YOU.
2	DR. LOMAX: I THINK TO REALLY KIND OF
3	SUMMARIZE IT IN A NUTSHELL WELL, ACTUALLY LET ME
4	JUST REMIND YOU ALL OF THE PROCESS. THIS DOCUMENT
5	WAS ALSO REVIEWED BY THE TASK FORCE THAT WAS SET UP
6	TO HELP US BRING THIS DRAFT FORWARD TODAY. SO WE'VE
7	HAD THE BENEFIT OF A ROUND OF COMMENTS AND
8	DELIBERATIONS FROM THE TASK FORCE IN RESPONSE TO
9	THOSE COMMENTS. WE'VE TRIED TO RESTRUCTURE THINGS A
10	BIT SO THEY HAVE A BIT MORE CLARITY AND ADDRESS SOME
11	OTHER CONCERNS THERE.
12	I THINK JUST TO REALLY AT THE SORT OF
13	HIGHEST LEVEL, WHAT THE FIRST REALLY THREE MAJOR
14	RECOMMENDATIONS ALL SORT OF CONVERGE AROUND IS TO
15	ENCOURAGE THE NIH TO ADOPT AN APPROACH THAT REALLY
16	DRAWS OFF THE ESTABLISHED SYSTEM OF OVERSIGHT. IT
17	DRAWS ON INSTITUTIONAL REVIEW BOARDS, BUT WOULD ALSO
18	NOT PRECLUDE THE STEM CELL RESEARCH OVERSIGHT
19	COMMITTEE MECHANISMS. SO WHAT WE'RE REALLY
20	EMPHASIZING IS A PROCESS FOR BEING ABLE TO ESTABLISH
21	THAT MATERIALS WERE DERIVED IN ACCORDANCE WITH CORE
22	ETHICAL PRINCIPLES, BUT BE VERY CAUTIOUS ABOUT THE
23	APPROACH THAT PRESCRIBES A VERY STRICT SET OF
24	EVALUATION CRITERIA THAT MAY DISQUALIFY OR OTHERWISE
25	HINDER THE USE OF SCIENTIFICALLY VALUABLE MATERIAL,

1	PARTICULARLY MATERIALS THAT ARE ALREADY IN EXISTENCE
2	THAT ARE PART OF THE RESEARCH STREAM.
3	AND IF YOU LOOK AT THE TABLES WE'VE ALSO
4	ATTACHED IN THIS DOCUMENT, WE'VE TRIED TO REALLY LAY
5	OUT THE MATERIALS THAT ARE ALREADY IN USE AND THE
6	UTILITY BOTH FOR USE IN SCIENCE AND TOWARDS RESEARCH
7	FOR PARTICULAR DISEASES.
8	(THE OPERATOR JOINS SAM HAWGOOD.)
9	DR. LOMAX: THE ONE FINAL THING I'D
10	SUGGEST IS THAT TOWARDS THE END OF THOSE
11	RECOMMENDATIONS, REALLY THE SORT OF SIX, SEVEN,
12	EIGHT, AND NINE, WE'VE MADE A NUMBER OF KIND OF
13	PROCESS, MORE SORT OF IMPLEMENTATION RECOMMENDATIONS
14	ABOUT HOW THE NIH COULD SUPPORT THROUGH REGISTRIES
15	AND ACCREDITATION PROGRAMS. I THINK SORT OF
16	HINDSIGHT, WE WOULD HOPE THAT IN THE FINAL DOCUMENT
17	THAT GOES TO NIH, WE MIGHT SORT OF CONSOLIDATE SOME
18	OF THOSE RECOMMENDATIONS A BIT. ONE, BECAUSE THEY
19	PERTAIN MORE TO IMPLEMENTATION RATHER THAN WHAT
20	THEIR OVERALL POLICY WOULD BE; AND, TWO, BECAUSE WE
21	JUST TRIED TO SORT OF LAY OUT EVERY SORT OF VARIABLE
22	AND EVERY SORT OF NUANCE. THEY TEND TO KIND OF
23	DILUTE THE RECOMMENDATIONS IN THE SORT OF FIRST
24	THIRD OF THE DOCUMENT, WHICH I BELIEVE ARE THE MOST
25	IMPORTANT FROM A SORT OF SUBSTANTIVE STANDPOINT. SO

1	WE DON'T WANT TO SORT OF DILUTE THE SUBSTANCE AND
2	IMPORTANCE OF THOSE RECOMMENDATIONS WITH SORT OF A
3	LONG LAUNDRY LIST OF ITEMS THAT ARE IMPORTANT BUT
4	SOMEWHAT DOWNSTREAM TO THE FORMULATION OF AN
5	ADDITIONAL POLICY.
6	SO I THINK I'LL JUST LEAVE IT AT THAT AND
7	TURN IT BACK OVER TO YOU, ART OR BOB.
8	MR. TORRES: I'LL TURN IT OVER TO BOB.
9	CHAIRMAN KLEIN: THANK YOU VERY MUCH. AND
10	I THINK WE OWE A GREAT DEAL OF GRATITUDE TO YOU,
11	GEOFF, FOR YOUR LEADERSHIP ON THIS, BOTH AT THE
12	AGENCY AND IN THE INTERGOVERNMENTAL ALLIANCE OF
13	STATES THAT HAVE
14	(THE OPERATOR JOINS DR. AZZIZ.)
15	CHAIRMAN KLEIN: DR. AZZIZ, YOU WERE NOT
16	ALONE, BUT WE HAVE JUST GONE THROUGH A QUICK SUMMARY
17	BY DR. LOMAX OF THE MATERIALS ON THE NIH PRINCIPLES
17 18	BY DR. LOMAX OF THE MATERIALS ON THE NIH PRINCIPLES THAT WE ARE PROMULGATING HERE FOR CONSIDERATION
18	THAT WE ARE PROMULGATING HERE FOR CONSIDERATION
18 19	THAT WE ARE PROMULGATING HERE FOR CONSIDERATION TODAY. I WOULD ALSO, TO SET THE FRAMEWORK, LIKE TO
18 19 20	THAT WE ARE PROMULGATING HERE FOR CONSIDERATION TODAY. I WOULD ALSO, TO SET THE FRAMEWORK, LIKE TO SAY THAT WHAT WE ARE GOING TO CONSIDER TODAY IS
18 19 20 21	THAT WE ARE PROMULGATING HERE FOR CONSIDERATION TODAY. I WOULD ALSO, TO SET THE FRAMEWORK, LIKE TO SAY THAT WHAT WE ARE GOING TO CONSIDER TODAY IS TAKING AN ACTION ON THESE GUIDELINES TO BE ABLE TO
18 19 20 21 22	THAT WE ARE PROMULGATING HERE FOR CONSIDERATION TODAY. I WOULD ALSO, TO SET THE FRAMEWORK, LIKE TO SAY THAT WHAT WE ARE GOING TO CONSIDER TODAY IS TAKING AN ACTION ON THESE GUIDELINES TO BE ABLE TO IMMEDIATELY POST THEM IN A DRAFT FORM SUBJECT TO
18 19 20 21 22	THAT WE ARE PROMULGATING HERE FOR CONSIDERATION TODAY. I WOULD ALSO, TO SET THE FRAMEWORK, LIKE TO SAY THAT WHAT WE ARE GOING TO CONSIDER TODAY IS TAKING AN ACTION ON THESE GUIDELINES TO BE ABLE TO IMMEDIATELY POST THEM IN A DRAFT FORM SUBJECT TO LEGAL REFINEMENT WITH COUNSEL AND HOPEFULLY WITH AN

1	SOME INTERPLAY WITH THE NIH ON SUGGESTED REFINEMENTS
2	OF LANGUAGE.
3	MS. KING: CHAIRMAN KLEIN, JUST TO CIRCLE
4	BACK TO THE ROLL CALL, WE MIGHT WANT TO DO THAT NOW.
5	WE HELD OFF ON THAT.
6	CHAIRMAN KLEIN: MELISSA, WHY DON'T YOU DO
7	THE ROLL CALL.
8	MS. KING: RICARDO AZZIZ.
9	DR. AZZIZ: PRESENT.
10	MS. KING: ROBERT BIRGENEAU. FLOYD BLOOM.
11	GORDON GILL FOR DAVID BRENNER.
12	DR. GILL: PRESENT.
13	MS. KING: SUSAN BRYANT.
14	DR. BRYANT: PRESENT.
15	MS. KING: MARSHA CHANDLER. MARCY FEIT.
16	MS. FEIT: HERE.
17	MS. KING: MICHAEL FRIEDMAN. LEEZA
18	GIBBONS. MICHAEL GOLDBERG.
19	MR. GOLDBERG: HERE.
20	MS. KING: SAM HAWGOOD.
21	DR. HAWGOOD: HERE.
22	MS. KING: BOB KLEIN.
23	CHAIRMAN KLEIN: PRESENT.
24	MS. KING: SHERRY LANSING.
25	MS. LANSING: HERE.
	7

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1	
1	MS. KING: GERALD LEVEY.
2	DR. LEVEY: HERE.
3	MS. KING: TED LOVE.
4	DR. LOVE: HERE.
5	MS. KING: ED PENHOET.
6	DR. PENHOET: HERE.
7	MS. KING: PHIL PIZZO.
8	DR. PIZZO: HERE.
9	MS. KING: CLAIRE POMEROY.
10	DR. POMEROY: HERE.
11	MS. KING: FRANCISCO PRIETO.
12	DR. PRIETO: HERE.
13	MS. KING: CARMEN PULIAFITO. ROBERT
14	QUINT. JEANNIE FONTANA.
15	DR. FONTANA: HERE.
16	MS. KING: DUANE ROTH.
17	MR. ROTH: HERE.
18	(MR. IRELAND JOINED DR. BIRGENEAU TO
19	THE CALL.)
20	MS. KING: JOAN SAMUELSON.
21	MS. SAMUELSON: PRESENT.
22	MS. KING: DAVID SERRANO-SEWELL. JEFF
23	SHEEHY.
24	MR. SHEEHY: HERE.
25	MS. KING: JON SHESTACK. AND OSWALD
	0
	8

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1	STEWARD, AND ART TORRES.
2	MR. TORRES: HERE.
3	MS. KING: AND ALSO, CHAIRMAN KLEIN, JUST
4	SO YOU KNOW, THERE ARE A FEW PEOPLE ON THE LINE THAT
5	I BELIEVE YOU KNOW HAVE TO LEAVE ON THE EARLIER
6	SIDE. AS VICE CHAIRMAN TORRES WAS SAYING EARLIER,
7	WE WILL TRY AND MOVE AS QUICKLY WE CAN TO THE ROLL
8	CALL VOTES FOR THOSE PEOPLE THAT NEED TO LEAVE
9	EARLY. SO I JUST WANTED TO REMIND YOU OF THAT AS
10	WELL.
11	MR. TORRES: THAT EARLY MOTION IS NOT TO
12	STIFLE DEBATE, BUT MERELY TO ALLOW THOSE PEOPLE WHO
13	CAN VOTE TO DO SO. SHERRY HAS TO LEAVE BY 8 O'CLOCK
14	AND OTHERS BY 8:30, SO WE'RE GOING TO TRY AND MOVE
15	IT ALONG.
16	MS. LANSING: OR I CAN JUST CAST MY VOTE.
17	MR. TORRES: THAT'S WHAT WE'RE TRYING TO
18	DO. SO WHY DON'T I MAKE A MOTION TO APPROVE THE
19	LANGUAGE THAT'S PUT FORWARD TO US BY DR. LOMAX AND
20	OTHER STAFF AS WELL WHO WORKED VERY HARD ON THIS AS
21	WELL.
22	MS. SAMUELSON: CAN YOU IDENTIFY YOURSELF?
23	MS. KING: THAT IS VICE CHAIRMAN ART
24	TORRES.
25	CHAIRMAN KLEIN: AND IS THERE A SECOND TO
	9

1	THAT MOTION?
2	DR. BRYANT: SECOND.
3	MS. KING: WHO WAS THE SECOND?
4	DR. BRYANT: SUE BRYANT.
5	MS. SAMUELSON: AND JOAN SAMUELSON.
6	CHAIRMAN KLEIN: SO DR. BRYANT IS THE
7	SECOND.
8	WHAT WE ARE DOING HERE IS PROCEEDING, AS
9	DISCUSSED BY ART TORRES, TO MAKE CERTAIN THAT WE GET
10	THE MOTIONS ON BOARD QUICKLY SO THAT IF WE HAVE TIME
11	CONSTRAINTS WITH INDIVIDUALS, WE CAN VOTE THOSE
12	VOTES, LEAVING THE ROLL OPEN WHILE WE GO THROUGH
13	ADDITIONAL DISCUSSION.
14	MS. BAUM: FOR CLARIFICATION, I THOUGHT
15	THE RESOLUTION WAS ALSO SUBJECT TO LEGAL REFINEMENT
16	BY COUNSEL WORKING WITH STAFF.
17	CHAIRMAN KLEIN: DOES THE MAKER OF THE
18	MOTION INCORPORATE THAT INTO HIS MOTION?
19	MR. TORRES: YES. SUBJECT TO THE
20	DELEGATION OF COUNSEL TO CONFORM CIRM'S RESPONSE TO
21	APPLICABLE LEGAL REQUIREMENTS.
22	CHAIRMAN KLEIN: AND POTENTIAL REFINEMENTS
23	THAT MAY OCCUR IN THE DIALOGUE WITH THE NIH.
24	MR. TORRES: THAT IS MY MOTION.
25	CHAIRMAN KLEIN: DOES THE SECOND CONFORM
	10

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1	TO THAT?
2	DR. BRYANT: SORRY. YES, I DO.
3	CHAIRMAN KLEIN: THANK YOU. LET ME ASK
4	HERE HOW MANY MEMBERS OF THE PUBLIC DO WE HAVE AND
5	AT WHICH LOCATIONS?
6	MS. KING: WE HAVE ONE HERE IN SAN
7	FRANCISCO AT THE CIRM.
8	MS. WERNETT: MARIJAYNE WERNETT IN SANTA
9	ROSA.
10	DR. TROUNSON: IT'S ALAN TROUNSON HERE.
11	UNFORTUNATELY I DIDN'T HAVE A CALL-IN NUMBER FOR AN
12	INTERNATIONAL SITE, SO I'VE JUST JOINED YOU, SO I'M
13	NOT SURE WHETHER YOU CAN BRING ME UP TO DATE ON WHAT
14	YOU ARE DOING, BUT IT WOULD BE HELPFUL.
15	CHAIRMAN KLEIN: ALAN, YOU ARE JOINING AS
16	JUST FOR SCIENTIFIC INPUT, NOT AS A VOTING MEMBER.
17	SO THAT IS APPROPRIATE. AND GEOFF LOMAX HAS JUST
18	REVIEWED THE RECOMMENDATIONS THAT YOU HAVE. THAT'S
19	THE STATUS AT THAT POINT. AND WE HAVE A MOTION
20	PENDING FOR APPROVAL WHICH INCLUDES AUTHORITY FOR
21	COUNSEL TO WORK ON LEGAL REFINEMENTS WITH THE
22	SCIENTIFIC STAFF AND TO DEVELOP (UNINTELLIGIBLE) IN
23	THE DIALOGUE WITH NIH.
24	DR. TROUNSON: THANK YOU.
25	CHAIRMAN KLEIN: LET ME ASK. IS THERE ANY
	11

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1	OTHER PUBLIC PRESENT AT ANY OF THE OTHER SITES?
2	OKAY. HEARING NO OTHER PUBLIC PRESENT, I'D LIKE TO
3	GET SOME QUICK PUBLIC INPUT IF IT'S AVAILABLE. IS
4	THERE PUBLIC INPUT IN SAN FRANCISCO?
5	MS. KING: NO. JUST FOR THE RECORD, I'D
6	LIKE TO NOTE IS ROBERT BIRGENEAU ON THE LINE?
7	DR. BIRGENEAU: YES, I AM.
8	CHAIRMAN KLEIN: OKAY. IS THERE PUBLIC
9	COMMENT AT SANTA ROSA?
10	MS. WERNETT: IT IS SANTA ROSA, BUT NO
11	COMMENT.
12	CHAIRMAN KLEIN: THANK YOU. FOR THE
13	RECORD, I WANTED TO QUICKLY MAKE IT CLEAR THAT
14	PUBLIC COMMENT WAS AVAILABLE. BUT ADDITIONAL MEMBER
15	COMMENT ON THE MOTION?
16	DR. PRIETO: BOB, JUST SORT OF A QUESTION
17	FOR GEOFF LOMAX. WERE YOU SUGGESTING THAT IT WOULD
18	IMPROVE OR IMPROVE OUR IMPACT IF WE HAD FEWER
19	RECOMMENDATIONS AND TO MERGE SOME OF THESE BECAUSE
20	IT SEEMED TO ME THAT SIX AND SEVEN SORT OF FLOW INTO
21	EACH OTHER AND EIGHT AND NINE SIMILARLY. I DON'T
22	KNOW IF THAT'S A MAJOR REVISION.
23	DR. LOMAX: THAT'S CORRECT. WE THOUGHT,
24	FOR THE BENEFIT OF PROVIDING KIND OF A VERY DETAILED
25	DESCRIPTION, WE WOULD NUMBER EVERYTHING INDIVIDUALLY

1	BECAUSE THEY DO VARY SLIGHTLY. BUT YOUR QUESTION IS
2	CORRECT. AGAIN, THERE'S SORT OF TWO POINTS THERE.
3	ONE IS BECAUSE OUR UNDERSTANDING FROM NIH IS THEY'RE
4	VERY SORT OF INTERESTED IN PURSUING AN APPROACH
5	SUGGESTED BY THOSE RECOMMENDATIONS; HOWEVER, THAT
6	APPROACH WILL REALLY BE MORE ON AN IMPLEMENTATION
7	FOOTING OF WHATEVER THE FINAL POLICY IS AS OPPOSED
8	TO FORMATIVE IN TERMS OF WHAT THE POLICY LOOKS LIKE.
9	AND SO, YES, THEY'RE RELATED TO EACH OTHER. THEY
10	COULD BE SORT OF GROUPED UNDER SOMETHING, A HEADING
11	SOMETHING THAT WOULD SAY LIKE MECHANISMS FOR
12	IMPROVING EFFICIENT IMPLEMENTATION, AND THEN WE
13	COULD KIND OF GROUP THEM THAT WAY AS OPPOSED TO
14	GIVING THEM SORT OF AN EQUIVALENT WEIGHT TO 1
15	THROUGH 3, 1 THROUGH 4, WHICH ARE REALLY, I THINK,
16	FROM A FORMATIVE STANDPOINT VERY IMPORTANT AT THIS
17	TIME TO KIND OF SEE IF WE CAN GET SEE IF NIH CAN
18	SORT OF INCORPORATE THAT INTO THE ACTUAL GUIDELINES.
19	SO IN SHORT, YES, FOR THE REASONS I JUST
20	DESCRIBED.
21	CHAIRMAN KLEIN: I WOULD CONSIDER,
22	FRANCISCO, THAT WITHIN THE CONTEXT OF THE MOTION,
23	THAT SCIENTIFIC STAFF WITH THE LEGAL COUNSEL COULD
24	CONSOLIDATE THESE RECOMMENDATIONS IN ORDER TO
25	PROVIDE MORE IMPACT TO THE DELIVERY.

1	DR. PRIETO: WE DON'T NEED A SPECIFIC
2	AMENDMENT TO THAT EFFECT?
3	CHAIRMAN KLEIN: I WOULDN'T THINK SO
4	BECAUSE WE'D BE CAPTURING THE CONTENT IN ANY CASE.
5	BUT IN TERMS OF, FRANCISCO, IF YOU WOULD LIKE TO
6	MAKE AN AMENDMENT THAT, IF THE STAFF CONCLUSION IS
7	TO HAVE AN EXPLICIT PRIORITY FOR THE RECOMMENDATIONS
8	AND INDICATE MORE OF AN IMPLEMENTATION STATUS FOR
9	FIVE AND FOLLOWING OR ANY OF THOSE IN THIS SECTION
10	FIVE OR FOLLOWING, WE COULD CERTAINLY HAVE AN
11	AMENDMENT TO ADDRESS THAT.
12	DR. PRIETO: WELL, I GUESS I WOULD I'D
13	MAKE SUCH AN AMENDMENT IF THE MAKER OF THE MOTION
14	ACCEPTS THAT AS A FRIENDLY AMENDMENT.
15	MR. TORRES: OF COURSE. NO PROBLEM.
16	CHAIRMAN KLEIN: AND THE SECOND?
17	DR. BRYANT: NO PROBLEM.
18	CHAIRMAN KLEIN: FINE. SO THE MOTION. IS
19	THERE ANY ADDITIONAL COMMENTS FROM MEMBERS?
20	MS. FEIT: RESTATE THE AMENDMENT, PLEASE.
21	THIS IS MARCY FEIT.
22	CHAIRMAN KLEIN: THE AMENDMENT, AS I
23	UNDERSTAND IT, IS THAT ITEMS 1 THROUGH 4 REPRESENT
24	THE PRIORITY POSITIONS THAT ARE CRITICAL TO
25	ACCOMPLISH, AND ITEMS 5 THROUGH 9, I BELIEVE, ARE
	14

1	DR. LOMAX: SIX THROUGH NINE.
2	CHAIRMAN KLEIN: SIX THROUGH NINE THANK
3	YOU FOR THE CORRECTION REPRESENT MORE
4	IMPLEMENTATION DIRECTIVES OR TECHNICAL LANGUAGE THAT
5	MIGHT BE PRESENTED AS EITHER OF SUBORDINATE
6	IMPORTANCE AND/OR IN A SEPARATE COMMUNICATION
7	(UNINTELLIGIBLE).
8	THE INTENT IS TO, I THINK, HAVE
9	CONSISTENCY BETWEEN CALIFORNIA AND TO THE DEGREE
10	POSSIBLE THE INTERSTATE ALLIANCE'S POSITIONS, BUT
11	WITH CALIFORNIA TAKING A LEADING POSITION. AND WHAT
12	STAFF IS REALLY SUGGESTING IS THEY WANT THE ABILITY
13	TO REALLY EMPHASIZE THE PRIORITY. IS IT 1 THROUGH
14	5, GEOFF THAT, YOU WANT TO EMPHASIZE THE PRIORITY
15	ON?
16	DR. LOMAX: YES.
17	CHAIRMAN KLEIN: THAT IS THE ESSENCE OF
18	THE AMENDMENT. IT HAS IN IT, MARCY, SOME DEGREE OF
19	DISCRETION AND DELEGATION TO THE SCIENTIFIC AND
20	LEGAL STAFF TO OPTIMIZE OUR POSITION AND COMMUNICATE
21	OUR COMMENTS.
22	ANY ADDITIONAL DISCUSSION WITH MEMBERS?
23	DR. FONTANA: I WANTED TO THANK GEOFF IN
24	PARTICULAR FOR ALL THE HARD WORK THAT HE'S DONE ON
25	PUTTING THIS ALL TOGETHER AND EVERYBODY WHO'S
	15

1	CONTRIBUTED.
2	I HAVE TO COMMENT ON THIS BECAUSE I
3	BELIEVE THAT ALL SCIENCE NEEDS TO BE FUNDED. AND I
4	UNDERSTAND THE POLITICS AROUND SOMATIC CELL NUCLEAR
5	TRANSFER AND WHY WE MAY OR MAY NOT WANT TO ADDRESS
6	THAT IN THIS PARTICULAR BILL. BUT IN LIGHT OF THAT,
7	I'M WONDERING IF IT'S POSSIBLE BECAUSE CIRM IS THE
8	ONLY INSTITUTE THAT LEGALLY WILL FUND SUCH RESEARCH.
9	AND I THINK IT WOULD BE IMPORTANT TO SUPPORT THAT.
10	BY OMITTING IT COMPLETELY IN THIS DOCUMENT, I JUST
11	AM WONDERING ARE WE NOT SUPPORTING SCNT BECAUSE OF
12	THAT? AND AS A POSSIBLE SOLUTION, WITHOUT PUTTING
13	IT IN A DRAFT, THAT WE COULD INCLUDE IN THAT
14	ORIGINAL PARAGRAPH WHERE WE TALK ABOUT CIRM, HOW IT
15	APPLAUDS THE NIH AND THAT CIRM WAS ESTABLISHED IN
16	2004 WHEN 59 PERCENT OF THE VOTERS AGREED TO SUPPORT
17	ETHICAL EMBRYONIC AND ADULT STEM CELL RESEARCH.
18	WOULD IT BE POSSIBLE TO INCLUDE JUST A SENTENCE IN
19	THERE THAT STATES THAT SOMATIC CELL NUCLEAR TRANSFER
20	ALONG WITH PARTHENOGENESIS AND IVF CELL-DERIVED
21	LINES UNDER ETHICAL GUIDELINES WERE VOTED BY THE
22	VOTERS APPROVED BY THE VOTERS OF CALIFORNIA?
23	CHAIRMAN KLEIN: SURE. FOR CONTEXT FOR
24	JEANNIE'S STATEMENT, I'D LIKE TO SAY THAT BECAUSE
2 E	JEANNIE HAS BEEN SHOU A CHAMBION OF SONT AND AN

16

1	ADVOCATE WITH NOT-FOR-PROFITS AND OTHER STATES
2	SPECIFICALLY, COUNSEL WANTED TO MAKE SURE THEY
3	VETTED WITH JEANNIE THE WHOLE RANGE OF HER
4	INVOLVEMENT WITH SCNT, WHICH THEY HAVE DONE. AND
5	SHE IS COMPLETELY AUTHORIZED TO DEAL ON POLICY. SHE
6	DOESN'T HAVE ANY CONFLICTS WE KNOW OF OR ANY
7	CONFLICTS OF ANY KIND THAT ANYONE HAS EVEN BROUGHT
8	TO ANYONE'S ATTENTION. SO THAT ISSUE HAS BEEN
9	CLEARED COMPLETELY. AND, JEANNIE, WE THANK YOU FOR
10	YOUR CHAMPIONSHIP OF SCNT WHICH CLEARLY ARE
11	SCIENTIFIC PRINCIPLES. IT'S IMPORTANT TO HAVE A
12	WHOLE RANGE OF SCIENTIFIC INQUIRY.
13	ARE THERE MEMBERS WHO WOULD LIKE TO
14	COMMENT ON JEANNIE'S POINT ABOUT MESSAGING OUTSIDE
15	THE CONTEXT OF THESE PRINCIPLES?
16	DR. PIZZO: AND I WOULD LIKE TO STRONGLY
17	ENDORSE AND SUPPORT JEANNIE'S COMMENTS. AND I
18	APPRECIATED HER ADVOCACY FOR THEM FROM THE ONSET.
19	DR. FONTANA: THANK YOU.
20	DR. LOVE: I AGREE WITH THAT POINT AS
21	WELL. I THINK JEANNIE HAS MADE AN IMPORTANT POINT
22	THAT SHOULD BE TAKEN INTO CONSIDERATION.
23	CHAIRMAN KLEIN: OKAY. JEANNIE, AS I
24	UNDERSTAND IT, IN THE CONVEYANCE DOCUMENTS YOU'RE
25	SUGGESTING WE INCORPORATE THIS IN THE STATEMENT OF

1	OUR CHARTER AND MISSION TO BRING IT AS A POINT OF
2	IMPORTANCE. IS THAT
3	DR. FONTANA: YES.
4	CHAIRMAN KLEIN: THE ESSENCE?
5	DR. FONTANA: YES.
6	CHAIRMAN KLEIN: AND SO THE SCIENTIFIC
7	STAFF AND THE LEGAL COUNSEL HAVE HEARD THE CONTEXT
8	OF IT. COUNSEL, IS JAMES HARRISON ON?
9	MR. HARRISON: YES.
10	CHAIRMAN KLEIN: JAMES, I DON'T THINK WE
11	NEED A MOTION TO INCORPORATE THAT UNLESS MEMBERS
12	WOULD LIKE TO DEBATE THAT AS A MATTER FOR A MOTION.
13	I HAD ASKED THAT QUESTION, BUT DO YOU SEE A REASON
14	TO HAVE TO NEED A MOTION TO INCORPORATE THAT?
15	MR. HARRISON: WHAT YOU MAY WANT TO
16	CONSIDER IS ASKING THE MAKER AND THE SECOND TO THE
17	MOTION TO INCLUDE ANOTHER SUBPOINT, WHICH IS TO
18	INCORPORATE A STATEMENT REGARDING CIRM'S AUTHORITY
19	TO FUND SCNT, IN THE INTRODUCTION AS PART OF THE
20	MOTION.
21	CHAIRMAN KLEIN: OKAY. SO THIS IS NOT AS
22	ONE OF OUR PRINCIPLES, BUT IT IS, IN FACT, IN THE
23	INTRODUCTION TO OUR AS A MATTER OF INFORMATION IN
24	OUR CONVEYANCE. IS THAT YOUR UNDERSTANDING, JAMES?
25	MR. HARRISON: YES, THAT'S CORRECT.
	10

1	CHAIRMAN KLEIN: FINE.
2	MR. TORRES: IT'S IN OUR PREAMBLE OF THIS
3	DOCUMENT, AND I SO MOVE THAT AMENDMENT AS THE MAKER
4	OF THE ORIGINAL MOTION.
5	CHAIRMAN KLEIN: AND DR. BRYANT?
6	DR. BRYANT: YES, I AGREE.
7	CHAIRMAN KLEIN: OKAY. ADDITIONAL
8	COMMENT?
9	MS. KING: JUST SO YOU KNOW, WE HAVE ABOUT
10	ONE MINUTE BEFORE WE WILL LOSE AT THE VERY LEAST
11	MEMBER LANSING.
12	MR. HARRISON: BOB, WOULD YOU LIKE ME TO
13	TRY TO RESTATE THE MOTION AS I UNDERSTAND IT AT THIS
14	POINT IN TIME?
15	CHAIRMAN KLEIN: IF YOU COULD RESTATE THE
16	MOTION, AND THEN WHAT I AM GOING TO DO IS I'M GOING
17	TO ASK FOR A ROLL CALL.
18	MR. HARRISON: AS I UNDERSTAND IT, THE
19	MOTION IS AS FOLLOWS: TO APPROVE CIRM'S RESPONSE TO
20	THE DRAFT NIH GUIDELINES SUBJECT TO A DELEGATION OF
21	AUTHORITY TO COUNSEL AND STAFF TO, NO. 1, CONFORM
22	CIRM'S RESPONSE TO APPLICABLE LEGAL REQUIREMENTS;
23	TWO, TO REFINE THE LANGUAGE IN DIALOGUE WITH NIH;
24	THREE, TO PRIORITIZE RECOMMENDATIONS 1 THROUGH 5
25	AND; FOUR, TO INCORPORATE A STATEMENT REGARDING
	10

1	CIRM'S AUTHORITY TO FUND SCNT IN THE PREAMBLE.
2	CHAIRMAN KLEIN: AS A STATEMENT OF
3	AUTHORITY AS AN IMPORTANT ELEMENT OF MEETING THE
4	ENTIRE SCIENTIFIC MISSION WHICH IS CRITICAL TO
5	ADVANCEMENT OF THIS FIELD.
6	MR. TORRES: I CALL FOR THE QUESTION.
7	CHAIRMAN KLEIN: DR. TROUNSON, ANY FINAL
8	COMMENT YOU'D LIKE TO MAKE?
9	DR. TROUNSON: NO. I THINK IT'S IMPORTANT
10	TO HAVE ICOC'S SUPPORT ON THIS DOCUMENT AND COMPLETE
11	IT AS QUICKLY AS POSSIBLE BECAUSE WE'RE NOW FALLING
12	WELL BEHIND THE OPPOSITION IN THIS AREA. SO I THINK
13	IF WE HAVE A VERY CLEAR MANDATE OF WHAT WE CAN DO,
14	WE CAN THEN ENCOURAGE, HOPEFULLY, OTHER SCIENTISTS
15	TO LOOK AT OUR DOCUMENT AND SUPPORT WHAT THEY FEEL
16	IS APPROPRIATE.
17	SO THE ONE THING THAT HAD SLIGHTLY
18	CONCERNED ME ABOUT PUTTING IN THE NUCLEAR TRANSFER
19	WAS IT WAS, YOU KNOW, IT WILL BE A LIGHTNING ROD TO
20	CRITICISM. BUT WHERE IT IS IN THE INTRODUCTION, I
21	THINK IT IS A FACT AND IT'S SUPPORTABLE. SO I THINK
22	THAT IT'S OKAY. UNFORTUNATELY THERE ARE NO CELL
23	LINES IN THAT AREA AVAILABLE AT THE MOMENT, SO IT
24	DOESN'T BECOME A MAJOR SCIENTIFIC ISSUE UNTIL THERE
25	IS.
	20

	DARRISTERS REPORTING SERVICE
1	DR. PIZZO: CAN I JUST QUICKLY MAKE ONE
2	COMMENT?
3	CHAIRMAN KLEIN: ABSOLUTELY.
4	DR. PIZZO: I JUST WANT TO SAY TWO THINGS.
5	FIRST IS I UNDERSTAND ALAN'S POINT, BUT I DO THINK,
6	DESPITE THE LIGHTNING ROD, IT IS IMPERATIVE FOR CIRM
7	TO STAND FOR WHAT IT BELIEVES IN.
8	AND THE SECOND THING IS THAT INDEPENDENT
9	OF OUR INSTITUTIONAL RESPONSE, WE'RE ENCOURAGING
10	INDIVIDUALS TO ALSO SEND IN RESPONSES TO THE NIH
11	WEBSITE. AND I WONDER WHETHER AT SOME POINT CIRM
12	SHOULDN'T DO THAT BECAUSE, AS IN ALL ACTIVITIES, AND
13	ALAN WILL KNOW THIS BETTER THAN MOST, THE NUMBER OF
14	RESPONSES IS GOING TO BE IMPORTANT IN ADDITION TO
15	INSTITUTIONAL RESPONSES.
16	CHAIRMAN KLEIN: IMMEDIATELY AFTER THIS
17	VOTE, I'M GOING TO HAVE OUR COUNSEL GIVE A CONTEXT
18	FOR WHAT WE CAN DO IN THAT REGARD, DR. PIZZO.
19	DR. PIZZO: GREAT. THANK YOU.
20	CHAIRMAN KLEIN: CALL THE QUESTION. AND
21	PLEASE CALL THE ROLL.
22	MS. KING: RICARDO AZZIZ. ROBERT
23	BIRGENEAU.
24	DR. BIRGENEAU: YES.
25	MS. KING: GORDON GILL.
	21
	21

21

1	DR. GILL: PRESENT.
2	MS. KING: SUSAN BRYANT.
3	DR. BRYANT: YES.
4	MS. KING: MARSHA CHANDLER. MARCY FEIT.
5	MS. FEIT: YES.
6	MS. KING: MICHAEL GOLDBERG.
7	MR. GOLDBERG: YES.
8	MS. KING: SAM HAWGOOD.
9	DR. HAWGOOD: YES.
10	MS. KING: BOB KLEIN.
11	CHAIRMAN KLEIN: YES.
12	MS. KING: SHERRY LANSING.
13	MS. LANSING: YES.
14	MS. KING: GERALD LEVEY.
15	DR. LEVEY: YES.
16	MS. KING: TED LOVE.
17	DR. LOVE: YES.
18	MS. KING: ED PENHOET.
19	DR. PENHOET: YES.
20	MS. KING: PHIL PIZZO.
21	DR. PIZZO: YES.
22	MS. KING: CLAIRE POMEROY.
23	DR. POMEROY: YES.
24	MS. KING: FRANCISCO PRIETO.
25	DR. PRIETO: YES.
	22

	DARRISTERS REPORTING SERVICE
1	MS. KING: JEANNIE FONTANA.
2	DR. FONTANA: YES.
3	MS. KING: DUANE ROTH.
4	MR. ROTH: YES.
5	MS. KING: JOAN SAMUELSON.
6	MS. SAMUELSON: YES.
7	MS. KING: DAVID SERRANO-SEWELL. JEFF
8	SHEEHY.
9	MR. SHEEHY: YES.
10	MS. KING: OSWALD STEWARD. ART TORRES.
11	MR. TORRES: YES.
12	DR. AZZIZ: MELISSA, THIS IS RICARDO. I
13	THINK I HIT MUTE WHEN I SAID YES.
14	CHAIRMAN KLEIN: COUNSEL, DO WE HAVE A
15	QUORUM?
16	MR. HARRISON: YES. THAT MOTION CARRIES
17	BY A VOTE OF 20 TO ZERO.
18	CHAIRMAN KLEIN: THANK YOU. LET'S GO TO
19	DR. PIZZO'S ITEM. AND THEN WHAT I'M GOING TO DO
20	MS. LANSING: I HAVE TO LEAVE, BUT I THINK
21	YOU HAVE A QUORUM FOR THE NEXT VOTE AS WELL.
22	MS. KING: WE DO. THANK YOU SO MUCH.
23	MS. LANSING: THANK YOU FOR DOING THIS
24	VOTE AT LEAST.
25	MR. TORRES: I JUST WANT TO POINT OUT TO
	23
	43

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1	CHECK THE NEW YORK TIMES. DON GIBBONS ALERTED ME TO
2	AN INCREDIBLE EDITORIAL, A LETTER TO THE EDITOR
3	NEW YORK TIMES EDITORIAL PAGE. VERY WELL DONE.
4	CHAIRMAN KLEIN: SO IN DIRECTING
5	SPECIFICALLY DIRECTED TO DR. PIZZO'S POINT, WHICH IS
6	QUITE WELL TAKEN AND VERY IMPORTANT, DR. PIZZO,
7	WE'VE TAKEN A CONSERVATIVE LEGAL POSITION AT THIS
8	POINT, THAT THE AGENCY, WHILE IT CAN POST A LETTER
9	WHICH OTHERS CAN LOOK AT AS A TEMPLATE AND IT IS
10	CLEARLY IMPORTANT THAT THERE BE CONSISTENCY BETWEEN
11	THE LETTERS COME IN SO THAT THEY CAN COUNTED AS PART
12	OF A BLOCK REPRESENTING A SCIENTIFIC POSITION, WE
13	CANNOT AS AN AGENCY PUT OUR LETTER OUT AS A MASS
14	MAILING, FOR EXAMPLE, AND ASK ALL OF OUR FIELD
15	ALL OF THOSE GRANTEES IN THE FIELD TO SUPPORT THIS
16	LETTER.
17	NOW, THOSE INDIVIDUALS MAY DECIDE TO DO
18	SO. AND BOARD MEMBERS ACTING AS INDIVIDUALS OUTSIDE
19	OF THIS BOARD AND NOT AS A BOARD CAN TAKE THEIR OWN
20	POSITIONS. LEGAL COUNSEL, JAMES HARRISON, COULD YOU
21	FURTHER COMMENT ON THAT?
22	MR. HARRISON: I THINK BOB HAS SUMMARIZED
23	IT QUITE WELL. AS MEMBERS OF THE BOARD, YOU ARE
24	FREE AS INDIVIDUALS TO URGE OTHERS TO CONTACT NIH TO
25	SUPPORT THE COMMENTS THAT CIRM HAS SUBMITTED. AND

1	CIRM IS OBVIOUSLY AUTHORIZED TO SUBMIT ITS OWN
2	COMMENTS TO NIH. BUT WE CAN'T USE THE AGENCY'S
3	RESOURCES TO URGE OTHERS TO CONTACT NIH ON OUR
4	BEHALF OR TO ADVOCATE THE POSITION THAT WE'VE
5	ADVANCED.
6	DR. PIZZO: JAMES AND BOB, THAT MAKES VERY
7	GOOD SENSE. I UNDERSTAND THAT. I WOULD JUST SAY
8	THAT FOLLOWING ACTUALLY THE SUGGESTION THAT BOB
9	MADE, I YESTERDAY IN MY BI-WEEKLY NEWSLETTER PUT OUT
10	A CALL TO EVERYBODY AT STANFORD OR WHO READS IT TO
11	SUBMIT RESPONSES. AND I WOULD THINK THAT AS
12	INDIVIDUAL INSTITUTIONS, LEADERS COULD WITH WHAT
13	VEHICLES THEY HAVE NOTIFY PEOPLE ABOUT THIS BECAUSE,
14	AS WE ALL RECOGNIZE, THE MANY THOUSANDS, I THINK,
15	OVER 7,000 TO DATE OF RESPONSES THAT HAVE COME INTO
16	THE NIH HAVE HAD A MAJORITY OF THEM AGAINST STEM
17	CELL RESEARCH FUNDING. AND I THINK WE NEED TO
18	CLEARLY COUNTER THAT AS INDIVIDUALS.
19	I REALIZE WE CAN'T DO IT THROUGH CIRM, BUT
20	WE COULD DO IT THROUGH OTHER CONTACTS.
21	CHAIRMAN KLEIN: I THINK THE HISTORY HAS
22	BEEN THAT TO DATE THE RESPONSES HAVE BEEN SEVEN TO
23	ONE NEGATIVE. IT IS A MATTER OF PUBLIC RECORD THAT
24	THE CATHOLIC BISHOPS CONFERENCE HAS PUT OUT A
25	WEBSITE AND A VERY SOPHISTICATED SYSTEM FOR

1	INDIVIDUALS WHO HAPPEN TO HAVE THAT POSITION TO
2	STATE THEIR POSITION ON TEMPLATES THAT THEY HAVE
3	PROVIDED.
4	ON A HISTORICAL BASIS DURING THE CLINTON
5	ADMINISTRATION, THERE WERE 55,000 RESPONSES WITH
6	ABOUT 90 PERCENT OF THEM BEING NEGATIVE. SO IT IS
7	VERY IMPORTANT AS CITIZENS AND AS SCIENTISTS AND AS
8	CLINICIANS THAT THE SCIENTIFIC AND CLINICAL
9	COMMUNITY BE PRESENT IN LARGE NUMBERS TO EXPRESS
10	THEIR POSITION.
11	DR. GILL: THE ADDRESS THAT COMMENTS
12	SHOULD BE SENT TO?
13	MS. KING: DR. GILL, DON GIBBONS AND I AND
14	GEOFF LOMAX CAN WORK WITH YOU ON THAT AFTER THE
15	CALL, IF THAT WORKS.
16	CHAIRMAN KLEIN: JAMES HARRISON, MY
17	UNDERSTANDING IS OUR LETTER WILL BE POSTED WITH THE
18	ADDRESS, SHOWING THE FULL ADDRESS TO WHOM IT'S GONE
19	TO THE ATTENTION OF.
20	MR. HARRISON: THAT'S CORRECT.
21	DR. PRIETO: BOB, WHAT WOULD BE THE
22	APPROXIMATE TIMEFRAME WHEN WE MIGHT SEE THAT, DO YOU
23	THINK?
24	CHAIRMAN KLEIN: IT WOULD BE POSTED TODAY
25	IN DRAFT AND WITHIN THE NEXT 72 HOURS IN FINAL FORM,
	26

1	BUT I WOULD SAY THAT THE DRAFT FORM WILL
2	SUBSTANTIVELY CONVEY THE POINTS. AND SO TO THE
3	EXTENT THAT PEOPLE ARE LOOKING TO THIS FOR
4	INTELLECTUAL LEADERSHIP, THE DRAFT REPRESENTS THE
5	POSITION.
6	DR. PIZZO: AND THE COMMENTS HAVE TO BE
7	PLACED BY MAY 26TH. AND ACTUALLY I'M GOING TO SEND
8	A LITTLE PARAGRAPH TO MELISSA RIGHT NOW THAT I SENT
9	OUT.
LO	MS. KING: VERY GOOD. THANK YOU, DR.
L1	PIZZO.
L2	DR. TROUNSON: BOB, CAN I ASK THROUGH YOU
L3	IF WE'RE ABLE TO SEND A COPY OF THE DRAFT TO
L4	INTERESTED SCIENTISTS WHO HAVE REQUESTED IT?
L5	CHAIRMAN KLEIN: WE SHOULD BE ABLE TO
L6	RESPOND TO ANY REQUEST.
L7	DR. PRIETO: COULDN'T WE SEND THAT OUT
L8	JUST FOR INFORMATIONAL PURPOSES WITHOUT URGING
L9	SPECIFIC ACTION?
20	DR. PIZZO: THAT'S WHAT I DID.
21	CHAIRMAN KLEIN: SO, DR. PRIETO, BECAUSE
22	WE WANT TO OPTIMIZE OUR ABILITY TO RESPOND, BUT
23	BECAUSE THE FACT PATTERNS ARE IMPORTANT, POTENTIALLY
24	YOU COULD ALLOW US TO WORK WITH COUNSEL TO TRY AND
25	RESPOND OPTIMALLY TO EACH OF THE REQUESTS.

1	DR. PRIETO: OKAY.
2	CHAIRMAN KLEIN: ALL RIGHT. SO IF WE CAN,
3	WE HAVE THE SAME DEADLINES HERE. I'D LIKE TO OPEN
4	THE SECOND ITEM ON THE AGENDA. IS DUANE ROTH ON?
5	MR. ROTH: YES, I AM.
6	MS. KING: FOR EVERYBODY ON THE CALL, THIS
7	IS ITEM NO. 4, AND YOU HAVE TWO DOCUMENTS RELATED TO
8	THIS ITEM.
9	CHAIRMAN KLEIN: WHAT I'D LIKE TO DO IS I
10	WANT TO OPEN THIS, GET INPUT AS TO OUR OUTREACH TO
11	THE SPONSORS. I WANT TO SEE IF THERE IS A MOTION
12	THAT CAN BE PUT ON THE TABLE, TAKE ANY VOTES FOR
13	INDIVIDUALS WHO HAVE A TIME CONSTRAINT, AND KEEP IT
14	OPEN GOING TO A FULL DISCUSSION WITH THE BOARD AND
15	WITH THE PUBLIC. I WILL BE TURNING THIS OVER AT THE
16	END OF THIS TO DUANE ROTH BECAUSE I HAVE TO CATCH A
17	PLANE.
18	BUT LET US INITIATE THIS ITEM ON FEDERAL
19	BIOSIMILAR LEGISLATION, HR 1427 AND 1548, BY
20	BRINGING THE BOARD UP TO DATE ON ADDITIONAL INQUIRY
21	THAT WAS DONE WITH THE STAFF. ART, COULD YOU REPORT
22	ON THAT?
23	MR. TORRES: YES, OF COURSE. I'VE SPOKEN
24	TO AND BEEN IN CONTACT WITH CONGRESSMAN WAXMAN'S
25	OFFICE, AND NANCY, OUR LEGAL COUNSEL HERE, AND ALSO

1	WITH JASON MAHLER, WHO IS THE CHIEF OF STAFF TO
2	CONGRESSMEMBER ESCHOO. AT THIS POINT CONGRESSWOMAN
3	ESCHOO HAS 73 COSPONSORS TO HER LEGISLATION AND
4	HENRY HAS TEN, BUT NEITHER OFFICE KNOWS WHEN THESE
5	BILLS WILL BE TAKEN UP OR IF THEY'LL BE PART OF A
6	LARGER HEALTH REFORM PACKAGE SINCE THE PRESIDENT IS
7	ARGUING FOR COST SAVINGS, WHICH THESE BILLS BY
8	IMPLICATION PROVIDE.
9	I THINK IT IS IMPORTANT THAT WE TAKE A
10	POSITION IN FAVOR OF THE ESCHOO BILL FOR MANY OF THE
11	REASONS THAT WE CITED AT OUR BOARD MEETING IN LOS
12	ANGELES. AND PRIOR TO THAT, TO ALSO RECOGNIZE THAT
13	I BELIEVE THIS BOARD HAS A RESPONSIBILITY, I THINK
14	EVERYONE AGREES, TO COMMENT ON ISSUES THAT ARE
15	IMPORTANT AS WE SEE THEM ON A PERIODIC BASIS. AND
16	THAT'S THE ESSENCE OF THIS MOTION. SIMPLY BECAUSE
17	WE DID NOT FEEL, AND DUANE CAN ENTER ON THIS AS
18	WELL, WE DID NOT FEEL THAT THE STATEMENT OF
19	PRINCIPLES WOULD BE ENOUGH TO BECOME A STAKEHOLDER
20	IN THE DEBATE, THAT WE NEEDED TO TAKE A POSITION,
21	NOT IN OPPOSING HENRY'S BILL, BUT MERELY SUPPORTING
22	ESCHOO'S BILL AND THE PRINCIPLES THAT WE FIND
23	CONSISTENT WITH THE VALUES AND THE INCENTIVES TO
24	PROVIDE FOR INVESTMENT OPPORTUNITIES FOR UP AND
25	COMING COMPANIES.

1	I ALSO WANTED TO CUE OVER TO DUANE AT THIS
2	POINT. I THINK DR. LOVE HAD A COMMENT AS WELL.
3	CHAIRMAN KLEIN: DUANE, IF WE COULD, CAN
4	WE DO DR. LOVE'S COMMENT AND THEN YOURS?
5	MR. ROTH: THAT WOULD BE FINE.
6	CHAIRMAN KLEIN: IS DR. LOVE ON?
7	DR. LOVE: I AM. AND I JUST WANT TO
8	SECOND MANY OF THE POINTS THAT ART MADE. I ACTUALLY
9	READ OVER THE STATEMENT OF PRINCIPLES. AND, QUITE
10	FRANKLY, I STRONGLY FELT AS YOU LOOK AT THE
11	COMPARISON THAT WE WERE GIVEN AT THE LAST MEETING
12	BETWEEN THE ESCHOO BILL AND THE WAXMAN BILL, THE
13	ICOC REALLY NEEDS TO STAND UP FOR THE ESCHOO BILL.
14	FUNDAMENTALLY I WOULD EMPHASIZE THAT
15	ESCHOO IS MUCH STRONGER ON THE INNOVATION, AND I
16	THINK THAT THIS BOARD AND OUR MISSION REALLY STANDS
17	BEHIND INNOVATION.
18	THE OTHER POINT I WOULD SAY IS SAFETY.
19	CONSISTENTLY, AS YOU READ THROUGH THE ESCHOO BILL,
20	THERE ARE MUCH STRONGER DIRECTIVES IN TERMS OF WHAT
21	NEEDS TO BE DONE TO APPROVE A BIOSIMILAR AROUND
22	ESTABLISHMENT OF SAFETY, AND THERE'S MUCH MORE
23	DIRECTION IN SUPPORT OF THE FDA TO TAKE A STAND ON
24	SAFETY OF DRUGS.
25	SO I THINK REALLY JUST FOR THE MAJOR
	30

1	PRINCIPLES OF SAFETY AND SUPPORTING OF INNOVATION AS
2	CRITICAL TO WHAT I WOULD INTERPRET AS OUR MISSION,
3	WE REALLY OUGHT TO SUPPORT THE ESCHOO BILL. AND I
4	THINK IT'S ENTIRELY CONSISTENT WITH THE VERY
5	PRINCIPLES THAT THE ICOC STANDS FOR, CIRM STANDS
6	FOR.
7	AND GETTING BACK TO PHIL'S POINT EARLIER,
8	I REALLY WOULD ENCOURAGE THE BOARD TO STAND UP FOR
9	ITS PRINCIPLES.
10	CHAIRMAN KLEIN: OKAY. DUANE.
11	MR. ROTH: I DON'T NEED TO REPEAT ANY OF
12	THE COMMENTS THAT HAVE BEEN SAID BECAUSE I AGREE
13	WITH THEM. I DID INVESTIGATE WHETHER PRINCIPLES
14	WOULD BE USEFUL, AND THE FEEDBACK I GOT IS IT'S WAY
15	TOO LATE FOR THAT.
16	THE SECOND THING I WANTED TO CALL THE
17	BOARD'S ATTENTION TO IS THE STATEMENT OF PRINCIPLES
18	THAT NANCY DRAFTED. AND IT WAS A SUPERB JOB. I
19	THINK IN THERE IS EMBEDDED, ESPECIALLY THE COMMENTS
20	THAT BOB MADE AT THE LAST MEETING, ABOUT THE
21	RESPONSIBILITY WE HAVE TO WORK WITH CONGRESS ON
22	ANYTHING THAT AFFECTS OUR MISSION. AND THEN THE
23	SECOND PART IS IN OUR DRAFT STRATEGIC PLAN, WHICH
24	YOU'VE ALL HAD A CHANCE TO LOOK AT, THERE'S SOME
25	VERY DEFINITIVE STATEMENTS IN THERE ABOUT WHAT WE
	21

1	SHOULD BE DOING IN SUPPORT OF GETTING OUR RESEARCH
2	FUNDED PROJECTS INTO PRODUCTS THAT CAN ACTUALLY HELP
3	PATIENTS.
4	SO I CAN'T THINK OF ANYTHING MORE
5	IMPORTANT TO BE AN INCENTIVE THAN SOMETHING LIKE
6	MARKET EXCLUSIVITY SO THAT PEOPLE ARE INCLINED TO
7	TAKE THE RISK TO GET THAT VERY FIRST PRODUCT ON THE
8	MARKET.
9	CHAIRMAN KLEIN: SO I'D LIKE TO OPEN THIS
10	TO OTHER BOARD COMMENTS.
11	DR. LEVEY: CAN I MAKE A COMMENT? WE'VE
12	READ ALL THESE, READ BOTH BILLS, AND I TALKED TO
13	DUANE, I TALKED TO TED. WE'VE TALKED A LOT OF THESE
14	THINGS OVER. THE ONLY CONCERN I HAVE, I AGREE WITH
15	EVERYTHING THEY'VE SAID SO FAR. THE ESCHOO BILL AS
16	A BILL IS FAR BETTER FOR INDUSTRY. BUT THE THING
17	THAT CONCERNS ME AND STILL CONCERNS ME IS THE FACT
18	THAT I REALLY FEEL UNEASY ABOUT TAKING A STAND
19	AGAINST A BILL SPONSORED BY HENRY WAXMAN BECAUSE HE
20	IS VERY EXTREMELY THOUGHTFUL. I HAVE NOT SPOKEN TO
21	HIM ABOUT THIS LEGISLATION. AND I JUST DON'T WANT
22	TO SEE THE CIRM CAUGHT IN A POLITICAL BATTLE BECAUSE
23	WE SEEM TO HAVE ENOUGH OF THOSE.
24	SO THAT'S MY ONLY CONCERN REGARDING THIS
25	BECAUSE I THINK WE DO HAVE TO MAKE SOME SORT OF
	22

1	STATEMENT ABOUT INNOVATION. AND HENRY'S BILL IS
2	JUST NOT GOING TO FAVOR INNOVATION FROM AN INDUSTRY
3	POINT OF VIEW.
4	AND THE LAST THING I WANT TO SAY, I'VE
5	SPOKEN WITH SHERRY ABOUT THIS, AND I KNOW SHE FEELS
6	SIMILAR TO WHAT I DO. THAT'S MY ONLY CONCERN WITH
7	REGARD TO THIS ISSUE.
8	DR. STEWARD: I'D LIKE TO SAY SOMETHING AT
9	SOME POINT.
10	MS. SAMUELSON: AND JOAN SAMUELSON WOULD
11	AS WELL.
12	CHAIRMAN KLEIN: DR. LEVEY, I THINK ONE OF
13	THE KEYS HERE IS THAT WHAT IS BEING PROPOSED IS TO
14	SUPPORT ESCHOO'S BILL AND NOT TAKE AN OPPOSITION
15	POSITION AGAINST WAXMAN, TO BE SUPPORTIVE
16	CONSTRUCTIVELY ON A POLICY BASIS WITH ESCHOO'S BILL,
17	POINTING OUT WHY WE THINK IT'S IMPORTANT TO OUR
18	MISSION, BUT NOT IN ANY WAY LOBBYING OR TAKING A
19	NEGATIVE POSITION ON WAXMAN.
20	SO IT IS THERE IS A DISTINCTION IN THE
21	LEGISLATIVE ARENA OF BEING A SUPPORTER OF ONE
22	APPROACH. THERE IS A DIFFERENT TYPE OF LEGISLATIVE
23	POSITION WHERE YOU STRONGLY ADVOCATE ONE APPROACH
24	AND STRONGLY OPPOSE AND NEGATIVELY CAMPAIGN AGAINST
25	ANOTHER APPROACH. THAT IS NOT BEING PROPOSED HERE.

1	SO THAT'S AN IMPORTANT DISTINCTION.
2	IT'S ALSO IMPORTANT THAT THE LEGISLATIVE
3	FEEDBACK IS QUITE CONSISTENT, THAT IF YOU DON'T TAKE
4	A POSITION ON A BILL, YOU ARE NOT A PRINCIPAL TO BE
5	DEALT WITH ON THIS BILL OR ANY OTHER BILL THAT
6	RELATES TO US, WHETHER IT RELATES TO FDA OR ANYTHING
7	ELSE, AND THAT THE PRINCIPLES ARE NOT GOING TO BE
8	TAKEN INTO CONSIDERATION BECAUSE THE LEGISLATION IS
9	MOVING TOO FAST IN THIS CONGRESS, AND IT IS TOO LATE
10	IN THE PROCESS TO WORK WITH THE VARIOUS AUTHORS ON
11	PRINCIPLES.
12	SO HOPEFULLY THAT DISTINCTION IS HELPFUL,
13	BUT WE HAVE A COUPLE OF OTHER BOARD MEMBERS WHO WANT
14	TO MAKE A COMMENT. JOAN. AND WHO WAS THE OTHER
15	BOARD MEMBER?
16	DR. STEWARD: THIS IS OS. I'D LIKE TO SAY
17	SOMETHING AS WELL.
18	MS. SAMUELSON: QUICK QUESTION FIRST. I
19	THINK, ART, YOU TALKED WITH THE MR. WAXMAN'S OFFICE.
20	I'M JUST WONDERING WHETHER ANYTHING CAME OF THAT
21	THAT INFORMED YOU FOR US ABOUT JUST WHY HE'S TAKING
22	A DIFFERENT POSITION OR WHERE HE'S HEADED WITH IT.
23	MR. TORRES: THE PROBLEM IS WE'VE NOT BEEN
24	ABLE TO CONNECT WITH THE POINT PERSON BECAUSE SHE'S
25	BEEN GONE FROM HENRY'S OFFICE. AND IT'S ALSO
	2.4

1	IMPORTANT TO NOTE, BECAUSE I WANT TO SECOND DR.
2	LEVEY AND SHERRY'S CONCERN, BECAUSE HENRY AND I HAVE
3	BEEN FRIENDS FOR OVER 35 YEARS. AND THAT'S WHY I
4	WOULD NEVER VOTE TO OPPOSE ANY OF HIS LEGISLATION
5	BECAUSE HE'S TOO IMPORTANT TO US AND TO THE STATE.
6	BUT I DO FEEL, AFTER TALKING TO DUANE AND
7	TO OTHERS AND TED AND OTHERS WHO HAVE ABOUT THIS,
8	THAT I WANTED TO MAKE SURE THAT HENRY'S OFFICE, WHO
9	I TALKED TO, RACHEL SHER, TO LET HER KNOW THAT WE
10	WANT TO LEAVE THE DOOR OPEN FOR DISCUSSIONS DOWN THE
11	ROAD, IF WE NEED TO. WE'RE NOT CLOSING TO THE DOOR
12	ON HENRY'S BILL. WE'RE JUST SAYING RIGHT NOW WE'RE
13	A LITTLE MORE COMFORTABLE WITH ANNA'S, AND WE FEEL
14	WE NEED TO TAKE A POSITION ON THAT, BUT IN NO WAY
15	REFLECTING OR IN NO WAY BREAKING COMMUNICATION OR IN
16	ANY WAY OPPOSING ANY OF HENRY'S LEGISLATION BECAUSE
17	I WOULD FEEL VERY UNCOMFORTABLE BEING PUT IN THAT
18	POSITION.
19	MS. SAMUELSON: RIGHT. AND SO THEN MY
20	COMMENT, I COMPLETELY AGREE. HE WAS MY FIRST MENTOR
21	WHEN I WENT TO THE HILL TO TRY TO GET SOMETHING
22	STARTED FOR PARKINSON'S. AND HE CAN BE A FORMIDABLE
23	OPPONENT, BUT HE'S A WONDERFUL MAN. AND SO IT WOULD
24	BE IN THE SPIRIT THAT YOU'RE OBVIOUSLY SUGGESTING,
25	ART, THAT WE WANT TO WORK WITH HIM AS MUCH AS WE CAN

1	IN VARIOUS WAYS. WE HAVE AS A PRIORITY IN OUR
2	LEGISLATION THE ACCESS TO PATIENTS OF ESTABLISHED
3	THERAPIES, WHICH IS WHAT HE'S GETTING AT, KEEPING
4	THINGS AFFORDABLE. SO OBVIOUSLY WE HAVE A CONCERN
5	ABOUT THAT TOO, BUT OUR OVERRIDING CONCERN IS
6	GETTING THERAPIES TO PATIENTS.
7	AND IT SOUNDS LIKE THE BIOSIMILAR PROBLEM,
8	WITHOUT BEING ADDRESSED, IS AN INSURMOUNTABLE
9	OBSTACLE AS I'M HEARING IT. IF BIOSIMILARS PLAY
10	ANYTHING LIKE THE ROLE OF GENERICS IN THE DRUG
11	WORLD, WE WILL NOT BE ABLE TO GET COMPANIES TO GO
12	INTO THE BUSINESS, AND THEY HAVE TO TO ESTABLISH
13	THERAPIES. SO IT SEEMS TO ME THAT THE ESCHOO BILL
14	IS THE ONLY WAY TO GO FOR US AS AN ORGANIZATION
15	BECAUSE OF WHAT OUR PRIORITIES ARE.
16	MR. TORRES: LET ME ALSO INTERJECT AND LET
17	YOU KNOW, WHICH SOME OF YOU KNOW ALREADY, SENATOR
18	KENNEDY HAS LEGISLATION WHICH IS VERY SIMILAR TO
19	ANNA'S BILL IN THE SENATE. AND SENATOR SCHUMER HAS
20	LEGISLATION VERY SIMILAR TO HENRY'S, SO THIS DEBATE
21	IS GOING TO GO ON. AND I WOULD ENVISION, WHETHER
22	IT'S PART OF A HEALTHCARE REFORM PACKAGE THAT COMES
23	OUT OF HENRY'S COMMITTEE OR WHETHER IT'S A
24	CONFERENCE COMMITTEE AT SOME POINT DOWN THE ROAD,
25	IT'S NOT OVER YET.

1	AND I THINK NANCY ALSO WAS IN TOUCH WITH
2	HENRY'S OFFICE AND WILL BE GETTING IN TOUCH WITH ANN
3	WITT, WHO IS HENRY'S POINT PERSON, WHO'S BEEN OUT OF
4	THE OFFICE, AND I WILL ALSO GET A PERSONAL CALL INTO
5	TO HENRY AS WELL TO LET HIM KNOW WHAT WE'RE UP TO
6	BECAUSE WE WANT TO CONTINUE TO WORK WITH THEM
7	BECAUSE THERE ARE GOING TO BE SO MANY OTHER ISSUES
8	DOWN THE ROAD THAT WE'RE GOING TO NEED HENRY ON.
9	AND, QUITE FRANKLY, HE'S GOING TO NEED OUR SUPPORT
10	тоо.
11	DR. LEVEY: I READ IN THE WALL STREET
12	JOURNAL THIS WEEK ACTUALLY A NUMBER OF
13	PHARMACEUTICAL FIRMS ARE STARTING THEIR OWN
14	BIOSIMILAR DIVISIONS, MERCK BEING ONE OF THEM.
15	MR. ROTH: MERCK IS GOING TO BE IN THE
16	BUSINESS, BUT THEY'RE GOING TO DO A FULL BATTERY OF
17	TESTS, TO TED LOVE'S COMMENT ABOUT SAFETY. THEY
18	AREN'T GOING TO JUST TRY TO TAKE SOMEBODY ELSE'S
19	DATA AND PUT THEIR LABEL ON TOP OF IT. THEY'RE
20	GOING TO DO THE FULL BATTERY OF TESTS, WHICH WILL
21	BRING PRICES DOWN. THERE WILL BE COMPETITION, AND
22	THAT WILL BE GOOD.
23	DR. STEWARD: THIS IS OS IF I COULD WEIGH
24	IN WITH, I GUESS, WHAT I WOULD HAVE TO CALL A
25	CONTRARIAN VIEWPOINT. AND IT ISN'T AGAINST ANY OF
	27

1	THE ISSUES THAT WE'RE TALKING ABOUT, BUT IT'S REALLY
2	ONE OF STRATEGY.
3	I GUESS THAT I HAVE TO SAY THAT I WOULD
4	PREFER THAT OUR ORGANIZATION BE SEEN OVER THE LONG
5	RUN AS ONE WHOSE OPINION REALLY COUNTS. AND BY THAT
6	I MEAN ONE THAT DOESN'T ACT ON ISSUES LIKE THIS IN A
7	WAY THAT I WOULD CALL LIKE A POLITICAL ACTION
8	COMMITTEE. I WOULD MUCH PREFER TO HAVE US SEEN AS
9	AN ORGANIZATION THAT ACTED WITH DUE CONSIDERATION
10	AND THAT WAS RESPECTED AS MUCH AS, FOR EXAMPLE, THE
11	NATIONAL ACADEMY. MAYBE THE NATIONAL ACADEMY HAS
12	WEIGHED IN ON THIS. IF SO, I STAND CORRECTED. BUT
13	IF THEY HAVE NOT, THEN I REALLY PREFER TO HAVE US
14	STRONGLY STATE PRINCIPLES. THOSE PRINCIPLES COULD
15	BE IDENTICAL TO ONE BILL OR ANOTHER, BUT JUST NOT
16	SPECIFICALLY SUPPORT ONE BILL OR ANOTHER.
17	MR. SHEEHY: I'D LIKE TO SUPPORT OS'
18	POSITION. I HAVE A LOT OF PROBLEMS SUPPORTING A
19	PARTICULAR BILL ESPECIALLY GIVEN THAT I HAD TROUBLE
20	SUPPORTING THE 12-YEAR TIMEFRAME, WHICH SEEMS
21	EXCESSIVE FROM A PATIENT'S POINT OF VIEW, AND IT'S
22	NOT GOING TO BE IN THE FINAL LEGISLATION GIVEN THAT
23	EEC, THE EUROPEAN COMMISSION, HAS A TEN-YEAR LIMIT.
24	AND SO THAT'S WHY I WAS MORE COMFORTABLE WITH THE
25	IDEA OF POSITIONS OF SUPPORTING PRINCIPLES AS

1	OPPOSED TO ACTUALLY TAKING A POSITION ON A BILL
2	BECAUSE I DON'T THINK CIRM SHOULD BE SUPPORTING THE
3	LONGEST TIME PERIOD FOR MAINTAINING EXCLUSIVITY
4	WHICH WILL LIMIT ACCESS, AT LEAST THE WAY OUR
5	PRESENT HEALTHCARE SYSTEM IS ARRANGED, AND GETTING
6	INTO THE MIDDLE OF THIS FIGHT. I AGREE WITH OS THAT
7	IT'S NOT REALLY OUR ROLE, AND IT'S TAKING US FAIRLY
8	DEEPLY INTO A LEGISLATIVE PROCESS THAT I'M NOT SURE
9	THAT WE REALLY IS A ROLE WE SHOULD REALLY BE
10	PLAYING.
11	CHAIRMAN KLEIN: IN TERMS OF THE
12	POSITIONS, THE NATIONAL ACADEMY IS NOT WITHIN ITS
13	CHARTER ABLE TO TAKE POSITIONS ON LEGISLATION THAT
14	I'M AWARE OF, OS.
15	ADDITIONALLY, IT IS IMPORTANT TO NOTE THAT
16	THERE'S BEEN QUITE A BIT OF RESEARCH AND SUBSTANTIAL
17	AMOUNT OF MATERIALS THAT HAVE BEEN LOOKED AT HERE.
18	AND, JEFF, IF WE TAKE A POSITION ON A BILL THAT'S
19	GOT 12 YEARS AND KENNEDY HAS A SIMILAR BILL, THE
20	ISSUE IS IS IT 12 OR IS IT FIVE. IF IT ENDS UP
21	BEING TEN, THAT'S THE LEGISLATIVE PROCESS, AS YOU
22	KNOW ONLY TOO WELL. BUT THE FUNDAMENTAL POINT IS
23	THAT THIS CHARTER WE HAVE WAS TO HAVE A DIRECT
24	INTERFACE WITH U.S. CONGRESS AND TAKE POSITIONS AS
25	WE HAVE ON THE STEM CELL LEGISLATION. AND THIS IS

1	AS IMPORTANT TO US IN GETTING TO PATIENTS.
2	BUT HAVING A TEN- OR A 12-YEAR PERIOD IS A
3	MINIMUM PERIOD TO GET ANY FINANCIAL SUPPORT,
4	PARTICULARLY IN A FIELD LIKE OURS WHERE YOU WILL RUN
5	THROUGH A PATENT PERIOD ALMOST COMPLETELY BEFORE YOU
6	GET TO THE POINT THAT YOU'VE GOT TO COMMERCIALIZE
7	PRODUCT. SO YOU'RE LOOKING FOR 15 YEARS ACTUALLY
8	MORE AS A MINIMUM FOR CAPITAL INVESTMENT.
9	IN ANY CASE, ARE THERE OTHER MEMBERS THAT
10	WOULD LIKE TO MAKE COMMENTS?
11	DR. LOVE: I'D LIKE TO RESPOND TO JEFF. I
12	THINK JEFF RAISED AN IMPORTANT POINT. AND WHAT I
13	WOULD SAY, JEFF, IS THAT IN MY CAREER IN INDUSTRY, I
14	ACTUALLY THINK INNOVATIVE COMPANIES HAVE DONE MUCH
15	MORE, QUITE FRANKLY, THAN GENERIC COMPANIES TO
16	PROVIDE ACCESS TO DRUGS. AND I CAN REMEMBER VERY
17	SPECIFICALLY THAT GENENTECH WAS VERY CONSISTENT
18	ABOUT MAKING OUR DRUGS AVAILABLE ABSOLUTELY FREE OF
19	CHARGE. WHEN I WAS A PRACTICING PHYSICIAN, I CAN
20	REMEMBER AT MASSACHUSETTS GENERAL WE PROVIDED A
21	GREAT DEAL OF FREE DRUGS THAT WAS PROVIDED AT NO
22	COST BY GENENTECH.
23	I THINK INNOVATIVE COMPANIES HAVE ACTUALLY
24	BEEN THE LEADERS MUCH MORE THAN GENERIC COMPANIES AT
25	PROVIDING ACCESS. IT'S IMPORTANT TO KEEP IN MIND
	40

1	THAT, MAYBE NOT SO MUCH WITH BIOLOGICS, BUT
2	CERTAINLY CONSISTENT WITH GENERICS, THE PATIENT
3	ULTIMATELY OFTEN SEES A COPAY. AND THE COPAY ISSUES
4	REALLY AREN'T AN ISSUE WHEN THE DRUGS ARE BEING
5	PROVIDED FREE OF CHARGE BY THE INNOVATOR. THEY ARE
6	AN ISSUE CONSISTENTLY WITH THE GENERIC COMPANY
7	BECAUSE, AT LEAST IN MY UNDERSTANDING, I'VE NEVER
8	SEEN A GENERIC COMPANY PROVIDE ANY KIND OF OFFSET
9	FOR THEIR COST.
10	AND THEN I WOULD GO BACK TO THE VERY
11	INITIAL POINT, AND THAT IS THAT I DON'T KNOW IF IT
12	WAS SHERRY, BUT SOMEONE AT THE LAST MEETING MADE THE
13	POINT THAT, FIRST, WE'VE GOT TO HAVE SOMETHING THAT
14	NEEDS TO BE MADE AVAILABLE. MY CONCERN RIGHT NOW,
15	TO BE VERY HONEST WITH YOU, IS THAT I THINK THAT
16	PRESSURES THAT ARE MOUNTING IN OUR INDUSTRY ARE
17	DRIVING PEOPLE AWAY FROM SUPPORTING THE COST AND
18	TAKING ON THE RISK OF DEVELOPING NEW THERAPIES. AND
19	THAT'S WHY I REALLY WOULD ENCOURAGE US, JUST
20	CONSISTENT WITH OUR INITIATIVE, TRYING TO GET
21	THERAPIES OUT THERE TO TRY TO BE MORE SUPPORTIVE OF
22	PROVIDING SOME INCENTIVE TO INNOVATORS WHICH SEEMS
23	TO BE DWINDLING EVERY DAY.
24	DR. PENHOET: CAN I ASK ART A QUESTION?
25	JUST A QUESTION. WE HEAR ON THE ONE HAND IT'S TOO

1	LATE TO ACTUALLY SET FORTH A SET OF PRINCIPLES TO
2	AFFECT THIS BECAUSE THE TRAIN HAS LEFT THE STATION.
3	THEN I ALSO HEARD YOU SAY, ART, THAT THIS IS GOING
4	TO GO ON FOR A LONG TIME, SO I'M A LITTLE BIT
5	CONFUSED ABOUT THE TIME PRESSURE ONE WAY OR THE
6	OTHER. CAN YOU HELP CLARIFY THAT FOR ME?
7	MR. TORRES: CERTAINLY. THE RESPONSE I
8	RECEIVED FROM CHIEF OF STAFF TO CONGRESSWOMAN ESCHOO
9	WAS THAT HENRY, AS IS HIS RIGHT TO DO AS CHAIR OF
LO	THIS COMMITTEE, HAS NOT SET A HEARING ON HIS BILL OR
L1	ON ANNA'S BILL, BUT IT COULD COME THROUGH THE BACK
L2	DOOR TO THE HEALTH REFORM LEGISLATION THAT HENRY
L3	WILL BE THE CHIEF AUTHOR OF FOR THE PRESIDENT COMING
L4	OUT OF THE COMMITTEE, AND THAT COULD BE IN A MORE
L5	TIMELY FASHION.
L6	SO AT THIS POINT I WANT TO MAKE SURE THAT
L7	WE ALL HAD THE SAME INFORMATION, AND THAT IS THAT WE
L8	DON'T KNOW WHEN THIS LEGISLATION IS GOING TO COME UP
L9	FOR HEARING, AND STAFF DOESN'T KNOW EITHER.
20	CHAIRMAN KLEIN: LET'S MAKE THIS CLEAR.
21	IT'S IMPORTANT TO HAVE POSITIONS ON THE RECORD
22	IMMEDIATELY BECAUSE WITH 73 CO-AUTHORS ON ESCHOO'S
23	BILL, THERE ARE THOSE THAT WOULD SUPPORT THE WAXMAN
24	BILL, BUT MAY WANT TO ATTACH IT TO OTHER
25	LEGISLATION. AND THEY NEED TO BE AWARE OF THE FACT

1	THAT BEST THAT FROM OUR VIEWPOINT OF GETTING
2	THERAPIES TO PATIENTS, WE ARE PROPOSING THAT WE NEED
3	A LONGER PERIOD IF THIS MOTION PASSES. IF IT FAILS,
4	WE ALSO MADE A STATEMENT.
5	BUT LET ME DO THIS. WE'RE GOING TO LOSE
6	MEMBERS AT THIS POINT. I'D LIKE TO KNOW IF THERE IS
7	A MOTION BECAUSE IF THERE'S A MOTION AND A SECOND, I
8	CAN OPEN THE ROLL AND THEN TAKE PUBLIC COMMENT, BUT
9	KEEP OPEN SO THAT THOSE WHO HAVE TO LEAVE CAN LODGE
10	THEIR VOTE AND WE WON'T LOSE OUR QUORUM FOR OUR
11	PROCESS.
12	MS. SAMUELSON: I'LL MAKE A MOTION TO
13	SUPPORT THE ESCHOO BILL.
14	DR. LOVE: I'LL SECOND THAT. THIS IS TED.
15	CHAIRMAN KLEIN: OKAY. MOTION MADE AND
16	SECONDED.
17	MR. TORRES: ALSO A FRIENDLY AMENDMENT TO
18	THAT MOTION, THAT READS SUPPORTING THE ESCHOO BILL,
19	BUT SUBJECT TO THE DELEGATION OF AUTHORITY TO THE
20	LEGISLATIVE SUBCOMMITTEE TO MONITOR LEGISLATION
21	RELATING TO BIOSIMILARS AND TO REFINE CIRM'S
22	POSITION CONSISTENT WITH CIRM'S STATEMENT OF
23	PRINCIPLES, PROPOSITION 71, AS THE LEGISLATION
24	EVOLVES IN THE HOUSE AND THE SENATE. I JUST WANT TO
25	MAKE SURE WE KEEP THE DOORS OPEN.

1	MS. SAMUELSON: I'LL ACCEPT THAT.
2	CHAIRMAN KLEIN: DOES THE SECOND ACCEPT
3	THAT?
4	DR. LOVE: YES, ABSOLUTELY.
5	CHAIRMAN KLEIN: OKAY.
6	MR. SHEEHY: CAN I ASK A QUESTION ABOUT
7	THE PROCESS? SO THE VOTE IS BEING HELD OPEN. AT
8	WHAT POINT DOES THE VOTE CLOSE?
9	CHAIRMAN KLEIN: THE VOTE WILL CLOSE HERE
10	ON THIS CALL. IT'S JUST BEING HELD OPEN SO THAT IF
11	THERE ARE MEMBERS THAT NEED TO LEAVE, BECAUSE WE'VE
12	BEEN TOLD THERE ARE SOME MEMBERS THAT NEED TO LEAVE
13	EARLY, THEY CAN LODGE THEIR VOTE.
14	MR. SHEEHY: WHEN DO THEY LODGE THEIR
15	VOTE? AFTER THE MEETING?
16	CHAIRMAN KLEIN: NO. NOW. DURING THE
17	MEETING, THEY HAVE TO LODGE THEIR VOTE. DURING THE
18	MEETING, FOR EXAMPLE, LIKE SHERRY HAD TO LEAVE, IF
19	WE WEREN'T QUITE DONE WITH DEBATE, SHERRY COULD HAVE
20	LODGED HER VOTE AND LEFT, AND THE DEBATE COULD HAVE
21	GONE FOR TEN MORE MINUTES BEFORE WE HAD THE ROLL
22	CALL.
23	MS. KING: AS LONG AS WE TAKE THIS VOTE
24	RIGHT NOW, WE MIGHT NOT HAVE TO HOLD IT UP.
25	MR. SHEEHY: THIS IS A NEW PROCESS. I'M
	4.4

1	NOT FAMILIAR WITH THIS.
2	MR. TORRES: IT'S A PROCESS THAT OCCURS IN
3	THE LEGISLATURE WHERE A ROLL CALL IS HELD OPEN UNTIL
4	THE MEETING IS ADJOURNED OF A COMMITTEE OR IN SOME
5	CASES
6	MR. SHEEHY: I KNOW THIS IS SUBJECT OF
7	MUCH CONTENTION AMONG CERTAIN INDIVIDUALS WHEN ROLL
8	CALLS ARE HELD OPEN FOR AN EXTENDED PERIOD OF TIME.
9	IT'S NOT A PROCESS WE'VE EVER USED BEFORE, SO I'M
10	NOT FAMILIAR WITH IT.
11	CHAIRMAN KLEIN: OKAY. IN TERMS OF TIME
12	PERIOD, JEFF, WE'RE TALKING ABOUT 15 MINUTES.
13	MS. KING: WE PROBABLY DON'T HAVE TO DO
14	IT, LIKE I SAID, IF WE TAKE THE VOTE RIGHT NOW.
15	MS. SAMUELSON: THIS IS JOAN. I'D LIKE TO
16	MAKE ONE MORE COMMENT, RESPONDING TO ED'S CONCERN
17	ABOUT SINCE THERE'S AVAILABLE TIME, WHY NOT HAVE A
18	STATEMENT OF PRINCIPLES FOR A WHILE.
19	WITH PENDING LEGISLATION, IT'S JUST TOO
20	LATE FOR THE FOLKS ON THE HILL TO CONSIDER OUR
21	INVOLVEMENT PERIOD, I THINK, IS THE WAY I WOULD PUT
22	IT.
23	MS. KING: WE ARE ABOUT TO LOSE VICE
24	CHAIRMAN TORRES, SO IF WE DID WANT TO MAKE USE OF
25	THAT PROCESS AND ALLOW HIM TO VOTE BEFORE HE LEAVES,

1	WE WOULD NEED TO DO THAT RIGHT NOW.
2	CHAIRMAN KLEIN: SO, JOAN, WITH YOUR LEAD,
3	PLEASE, ARE THERE ANY OTHER MEMBERS THAT NEED TO
4	LEAVE?
5	DR. POMEROY: I HAVE TO LEAVE RIGHT NOW.
6	CHAIRMAN KLEIN: WILL YOU TAKE THE ROLL
7	CALL, PLEASE. WHO NEEDS TO LEAVE?
8	MS. KING: DR. POMEROY AND ART TORRES.
9	SHOULD I TAKE JUST THEIR VOTES, CHAIRMAN
10	KLEIN, OR DO YOU WANT ME
11	CHAIRMAN KLEIN: ONLY THOSE INDIVIDUALS
12	THAT NEED TO LEAVE.
13	MS. KING: DR. POMEROY, YOU VOTE.
14	DR. POMEROY: I'M GOING TO ABSTAIN BECAUSE
15	I'M NOT COMFORTABLE VOTING UNTIL I HEAR THE ENTIRE
16	CONVERSATION. THANK YOU.
17	MS. KING: ART TORRES.
18	MR. TORRES: AYE.
19	MS. KING: THANK YOU.
20	DR. FONTANA: I HAVE TO LEAVE AT NINE. SO
21	IF THIS IS NOT DONE BY THEN, I VOTE YES IN FAVOR OF
22	ESCHOO.
23	DR. PENHOET: THIS IS ED. CAN I CLARIFY?
24	JOAN PUT WORDS IN MY MOUTH. I WASN'T RECOMMENDING
25	THE PRINCIPLES. I WAS SIMPLY SEEKING CLARIFICATION.

1	MS. SAMUELSON: THAT'S WHAT I ASSUMED,
2	YES.
3	CHAIRMAN KLEIN: THANK YOU. THANK YOU
4	VERY MUCH, DR. PENHOET.
5	OKAY. IS THERE PUBLIC COMMENT IN SAN
6	FRANCISCO?
7	MS. KING: NONE HERE.
8	CHAIRMAN KLEIN: IS THERE PUBLIC COMMENT
9	IN SANTA ROSA?
10	MS. WERNETT: NO.
11	CHAIRMAN KLEIN: IS THERE PUBLIC COMMENT
12	AT ANY OF THE OTHER SITES? OKAY. IS THERE
13	ADDITIONAL ARE THERE ADDITIONAL MEMBERS WHO WOULD
14	LIKE TO MAKE COMMENTS? ALL RIGHT. HEARING NO
15	ADDITIONAL MEMBERS, IT APPEARS THAT WE CAN PROCEED
16	WITH THE ROLL CALL. I JUST WANTED TO MAKE SURE THAT
17	WE ACCOMMODATED ANY ADDITIONAL MEMBER COMMENTS.
18	DR. AZZIZ: BEFORE THE ROLL CALL, COULD WE
19	RESTATE THE MOTION PLEASE, CLEARLY?
20	MR. HARRISON: THE MOTION IS TO ENDORSE
21	THE ESCHOO BILL HR 1548 SUBJECT TO THE DELEGATION OF
22	AUTHORITY TO THE LEGISLATIVE SUBCOMMITTEE TO MONITOR
23	THE LEGISLATION RELATING TO BIOSIMILARS AND TO
24	REFINE CIRM'S POSITION CONSISTENT WITH THE STATEMENT
25	OF PRINCIPLES AND PROP 71 AS THE LEGISLATION EVOLVES
	47

	DARRISTERS REPORTING SERVICE
1	IN THE HOUSE AND THE SENATE.
2	CHAIRMAN KLEIN: WITH THE INTENT TO KEEP
3	THE DOORS OPEN IN COMMUNICATION WITH THE WAXMAN
4	OFFICE IN PARTICULAR.
5	DR. AZZIZ: WE ARE NOT VOTING ON THE
6	STATEMENT OF PRINCIPLES, ITEM 4.
7	CHAIRMAN KLEIN: WE ARE NOT. WE ARE NOT.
8	THIS IS TO TAKE A VOTE IN SUPPORT OF ESCHOO. IT IS
9	NOT A VOTE THERE IS NO PART OF THIS MOTION THAT
10	HAS AN OPPOSITION TO WAXMAN, AND THERE IS A DESIRE
11	TO CONTINUE THAT DISCUSSION. OKAY.
12	COULD YOU CONTINUE WITH THE ROLL CALL
13	GIVEN THAT THERE'S NO ADDITIONAL MEMBERS. AND DAVID
14	SERRANO-SEWELL WASN'T AVAILABLE FOR THE LAST VOTE,
15	BUT HE IS HERE IN THIS MEETING.
16	MS. KING: RICARDO AZZIZ.
17	DR. AZZIZ: ABSTAIN.
18	MS. KING: ROBERT BIRGENEAU.
19	DR. BIRGENEAU: YES.
20	MS. KING: GORDON GILL.
21	DR. GILL: YES.
22	MS. KING: SUSAN BRYANT.
23	DR. BRYANT: YES.
24	MS. KING: MARSHA CHANDLER. MARCY FEIT.
25	MS. FEIT: YES.
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i	BANKISTERS REPORTING SERVICE
1	MS. KING: MICHAEL GOLDBERG.
2	MR. GOLDBERG: YES.
3	MS. KING: SAM HAWGOOD.
4	DR. HAWGOOD: YES.
5	MS. KING: BOB KLEIN.
6	CHAIRMAN KLEIN: YES.
7	MS. KING: GERALD LEVEY.
8	DR. LEVEY: NO.
9	MS. KING: TED LOVE.
10	DR. LOVE: YES.
11	MS. KING: ED PENHOET.
12	DR. PENHOET: YES.
13	MS. KING: PHIL PIZZO.
14	DR. PIZZO: YES.
15	MS. KING: FRANCISCO PRIETO.
16	DR. PRIETO: YES.
17	MS. KING: DUANE ROTH.
18	MR. ROTH: YES.
19	MS. KING: JOAN SAMUELSON.
20	MS. SAMUELSON: YES.
21	MS. KING: DAVID SERRANO-SEWELL.
22	MR. SERRANO-SEWELL: YES.
23	MS. KING: JEFF SHEEHY. OSWALD STEWARD.
24	DR. STEWARD: NO.
25	DR. PIZZO: WONDER IF JEFF IS ON MUTE.
	40
	49

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1	CHAIRMAN KLEIN: OKAY. COUNSEL, WHAT IS
2	THE VOTE?
3	MR. HARRISON: THE MOTION CARRIES BY A
4	VOTE OF 16 YESES, TWO NOES, AND TWO ABSTENTIONS.
5	DR. STEWARD: I REALLY HAVE TO RAISE THE
6	ISSUE THAT JEFF SHEEHY RAISED. WE HAVE NEVER DONE
7	THIS PROCESS BEFORE. AND IF WE EVER HAD BEEN ABLE
8	TO, WE WOULD HAVE AVOIDED ALL KINDS OF PROBLEMS AT
9	ICOC MEETINGS WITH PEOPLE LEAVING EARLY. I JUST
10	DON'T UNDERSTAND WHY THIS PROCESS HAS BEEN INVOKED
11	NOW TODAY, AND I HAVE TO SAY IN A VERY STRANGE WAY.
12	MR. ROTH: OS, IT HAS TO DO WITH A SINGLE
13	MOTION. YOU CAN'T LEAVE THE MEETING AND VOTE ON
14	ANYTHING ELSE.
15	DR. STEWARD: WE HAVE THIS PROBLEM ALL THE
16	TIME IN ICOC MEETINGS WHEN THERE ARE TOPICS UNDER
17	DISCUSSION.
18	MR. ROTH: NO. NO.
19	DR. STEWARD: WE DO. WHEN THERE ARE
20	TOPICS UNDER DISCUSSION, WHEN A VOTE IS IMMINENT AND
21	PEOPLE HAVE TO CATCH A PLANE, WE COULD EASILY DO
22	THIS AND AVOID THE LOSS OF MEMBERS AND A LOSS OF A
23	QUORUM. I DON'T UNDERSTAND WHY IT'S BEING INVOKED
24	HERE AND NOT ANY OTHER TIME.
25	DR. PIZZO: I THINK IT'S A BIGGER QUESTION
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1	BECAUSE I THINK IT ALSO IMPACTS ON THE QUALITY OF
2	THE DISCUSSION AS WELL.
3	DR. STEWARD: I ABSOLUTELY AGREE.
4	DR. PIZZO: WHEREAS, I LIKE THE IDEA OF
5	FACILITATING THE PROCESS, I THINK AT A SUBSEQUENT
6	ICOC MEETING WE SHOULD DISCUSS IT BECAUSE IT DOES
7	IMPACT ON OUR CULTURE AND HOW WE DO THINGS.
8	DR. LEVEY: I'D JUST LIKE TO ADD TO WHAT
9	PHIL SAID BECAUSE I REALLY AGREE WITH THAT AND I
10	AGREE WITH WHAT OS IS SAYING. I WAS REALLY
11	RELUCTANT TO VOTE NO, BUT I FELT WE'RE JUMPING IN
12	HERE MUCH TOO QUICKLY.
13	DR. PIZZO: I HAVE THE SAME REACTION EVEN
14	WITH REGARD TO MY VOTE. I THINK WE'VE BEEN ENRICHED
15	OVER THE YEARS BY HEARING EACH OTHER'S POINT OF
16	VIEW. I WORRY THAT WE'RE GOING TO WIND UP COMING IN
17	WITH PREFIXED IDEAS THAT DON'T NECESSARILY ALLOW
18	THEMSELVES TO BE ATTENTIVE TO NEW INSIGHTS.
19	CHAIRMAN KLEIN: SO THIS IS BOB. I'D LIKE
20	TO SAY THE VERY REASON THAT WE DON'T USE THIS AT
21	REGULAR ICOC MEETINGS IS TWOFOLD. A, THAT WE DON'T
22	WANT TO DO THIS EARLY IN THE DAY WHEN PEOPLE
23	ANNOUNCE QUITE UNEXPECTEDLY AT TIMES THAT THEY NEED
24	TO LEAVE BECAUSE WE HAVEN'T HAD THE CHANCE FOR A
25	DISCUSSION. THIS ITEM, AS YOU KNOW, WAS DISCUSSED
	E1

1	AT A PRIOR BOARD MEETING AS WELL AS IN THIS MEETING.
2	DR. STEWARD: LET ME JUST POINT OUT, BOB,
3	THE VOTE WENT THE OTHER WAY IN THAT PRIOR VOTE,
4	WHICH IS EXACTLY THE REASON I'M A LITTLE OFFENDED BY
5	THIS.
6	CHAIRMAN KLEIN: HOLD ON. EXCUSE ME.
7	POINT OF ORDER HERE. LISTEN, THE SECOND REASON IS
8	THAT THIS IS THERE ARE ONLY TWO ITEMS ON THIS
9	AGENDA. IT WAS UTILIZED IN A VERY LIMITED SENSE IN
10	THE CASE WHERE THE FACT IS IT IS ONLY FOR TEN OR 15
11	MINUTES, WHICH I SAID WHEN THE QUESTION WAS RAISED
12	WHEN WE HAVE HAD SUBSTANTIAL MATERIALS DISBURSED AND
13	WE HAVE HAD THE DEBATE HAD ALREADY OCCURRED. BUT
14	IT IS WE WILL DEFINITELY DISCUSS THIS AS AN ITEM
15	AS TO WHETHER WE CAN USE THIS PROCESS IN A LIMITED
16	MANNER.
17	AND, FRANKLY, TO THE EXTENT THAT WE HAVE
18	NONCONTROVERSIAL ISSUES AT THE END OF AN ICOC
19	MEETING, NONCONTROVERSIAL ISSUES, THEN IT WOULD SEEM
20	TO BE APPROPRIATE.
21	THE OTHER REASON IS THAT, AS NOTED, THERE
22	WAS NO PUBLIC COMMENT HERE THAT WAS PENDING. THERE
23	WAS NO PUBLIC CONTROVERSY AT THIS MEETING. SO I'M
24	TRYING TO BE VERY CAREFUL AND SENSITIVE TO USE IT IN
25	A VERY LIMITED ROLE, BUT WE CERTAINLY WILL DEBATE IT

1	AND HAVE DISCUSSION.
2	I'D LIKE TO THANK EVERYONE FOR
3	PARTICIPATION IN THE MEETING. AND I'D LIKE TO THANK
4	THE MEMBERS THAT WORKED HARD ON THE RESEARCH AND THE
5	BACKGROUND FOR THIS, AND WE'LL LOOK FORWARD TO THE
6	NEXT MEETING.
7	MS. KING: WE DO HAVE A PUBLIC COMMENT
8	HERE IN SAN FRANCISCO AT THIS TIME. THIS IS DON
9	REED.
10	MR. REED: I'D JUST LIKE TO ADD ON THE
11	IMPORTANCE OF THE INDIVIDUAL PARTICIPATION OF BOARD
12	MEMBERS AND ALL OF YOUR FRIENDS, RELATIVES, FAMILY
13	MEMBERS. THE BILL, THE NIH GUIDELINES VOTE ON THIS
14	WILL BE WIDELY PUBLICIZED. IT'S GOING TO USED AS AN
15	ARGUMENT AGAINST THE RESEARCH. IT'S GOING TO BE
16	VERY IMPORTANT IN STATE EFFORTS. (UNINTELLIGIBLE)
17	BORDERLINE OF YES, NO, WE CAN SAY, LOOK, (INAUDIBLE)
18	IT'S REALLY IMPORTANT THAT EVERYBODY AS AN
19	INDIVIDUAL TAKE THOUGHT AS TO HOW THEY CAN AFFECT
20	THIS PROCESS.
21	CHAIRMAN KLEIN: THANK YOU ALL.
22	(THE MEETING WAS THEN CONCLUDED AT
23	08:45 A.M.)
24	
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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 TELEPHONIC PROCEEDINGS BEFORE THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS SPECIAL MEETING ON MAY 12, 2009, 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 BARRISTER'S REPORTING SERVICE 1072 BRISTOL STREET SUITE 100 COSTA MESA, CALIFORNIA (714) 444-4100