BEFORE THE LEGISLATIVE SUBCOMMITTEE

OF THE

INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE TO THE

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

REGULAR MEETING

LOCATION: AS INDICATED ON THE AGENDA

DATE: MONDAY, APRIL 27, 2009

7:30 A.M.

REPORTER: BETH C. DRAIN, CSR

CSR. NO. 7152

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2

	DARRISTERS REPORTING SERVICE
1	MONDAY, APRIL 27, 2009
2	7:30 A.M.
3	
4	CHAIRMAN KLEIN: MELISSA, WOULD YOU TAKE
5	THE ROLL, PLEASE.
6	MS. KING: SUSAN BRYANT. MICHAEL
7	GOLDBERG. BOB KLEIN.
8	CHAIRMAN KLEIN: HERE.
9	MS. KING: CLAIRE POMEROY.
10	DR. POMEROY: HERE.
11	MS. KING: FRANCISCO PRIETO. JEANNIE
12	FONTANA FOR JOHN REED.
13	DR. FONTANA: HERE.
14	MS. KING: DUANE ROTH.
15	DR. ROTH: HERE.
16	MS. KING: JOAN SAMUELSON. JEFF SHEEHY.
17	MR. SHEEHY: HERE.
18	MS. KING: ART TORRES.
19	MR. TORRES: HERE.
20	MS. KING: WE DO NOT YET HAVE A QUORUM.
21	WE'RE WAITING FOR A COUPLE OF OTHER PEOPLE TO JOIN
22	US; BUT GIVEN THAT SOME MEMBERS HAVE A HARD STOP,
23	YOU MIGHT JUST WANT TO BEGIN THE DISCUSSION.
24	WHO JUST JOINED?
25	DR. TROUNSON: IT'S ALAN TROUNSON
	3

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1	REJOINING.
2	CHAIRMAN KLEIN: ALAN, IF YOU JOIN TWICE,
3	WE CAN'T COUNT YOU TWICE.
4	ALL RIGHT. DUANE
5	MR. ROTH: YES.
6	CHAIRMAN KLEIN: GIVEN THE HARD STOP,
7	CLAIRE POMEROY SPECIFICALLY HAS A HARD STOP. AND,
8	CLAIRE, I WANTED TO MAKE SURE. DID YOU WANT TO BE
9	ON THE MEDICAL AND ETHICAL STANDARDS NIH TASK FORCE?
10	DR. POMEROY: BOB, I REALLY APPRECIATE THE
11	OPPORTUNITY, BUT I THINK I SHOULD PASS AND DEFER TO
12	MY COLLEAGUES.
13	CHAIRMAN KLEIN: KNOWING YOU HAD TO LEAVE,
14	I WANTED TO JUST MAKE SURE I ASKED THAT
15	SPECIFICALLY. OKAY. CLAIRE HAS TO LEAVE AT ABOUT
16	EIGHT. SO, DUANE, COULD YOU LEAD OFF? WE DO NOT
17	YET HAVE A QUORUM, SO WE'RE NOT GOING TO CONDUCT THE
18	ROLL CALL YET, BUT WE CAN BEGIN DISCUSSION; IS THAT
19	RIGHT, COUNSEL?
20	MR. HARRISON: YES.
21	CHAIRMAN KLEIN: COUNSEL AGREES. SO,
22	DUANE, COULD YOU LEAD OFF ON CONSIDERATION OF THE
23	FEDERAL LEGISLATION?
24	MR. ROTH: YES. I THINK EVERYBODY HAS
25	LOOKED AT OR HOPEFULLY HAD A CHANCE TO LOOK AT THE

1	COMPETING BILL COMPARISON. THERE ARE TWO BILLS FOR
2	BIOGENERICS OR BIOSIMILARS, AS THEY'RE NOW CALLED.
3	ONE IS FROM CHAIRMAN WAXMAN AND OTHER IS FROM
4	CONGRESSWOMAN ESCHOO. SO WAXMAN IS 1427, HR 1427,
5	AND ESCHOO IS HR 1548.
6	BOTH OF THESE BILLS ESTABLISH A PATHWAY
7	FOR GENERIC BIOLOGICALS TO GET ONTO THE MARKET USING
8	THE INNOVATOR'S DATA. IN OTHER WORDS, THE FIRST
9	PRODUCT THAT WENT THROUGH THE FOOD AND DRUG
10	ADMINISTRATION RECEIVED APPROVAL. BOTH ARE
11	ATTEMPTING AT SOME POINT, OBVIOUSLY AFTER PATENTS
12	HAVE EXPIRED, WHICH IS A COMPLETELY SEPARATE ISSUE,
13	THE FDA WOULD BE ABLE TO APPROVE BIOLOGICAL PRODUCTS
14	WITH THE ORIGINAL INNOVATOR DATA AS THE BASIS FOR
15	SAFETY AND EFFICACY PROVIDED THEY CAN PROVE THAT THE
16	PRODUCTS ARE, IN FACT, SIMILAR. THEY DON'T HAVE TO
17	BE IDENTICAL, BUT SIMILAR.
18	THE DIFFERENCE BETWEEN THESE TWO, THERE
19	ARE SEVERAL SUBTLE DIFFERENCES, BUT THE MAIN
20	DIFFERENCE IS THE NUMBER OF YEARS THE INNOVATOR'S
21	DATA CANNOT BE USED. IN THE WAXMAN BILL, IT VARIES
22	AND THERE ARE SEVERAL NUANCES TO IT, BUT ESSENTIALLY
23	I THINK IT'S FIVE YEARS, AND IN THE ESCHOO BILL IT'S
24	12 YEARS. SO THERE'S A LONGER DATA EXCLUSIVITY WITH
25	ESCHOO VERSUS WAXMAN.

1	AND THE REASON THAT'S KEY FOR US AND THE
2	REASON WE'RE CONSIDERING THIS AND TAKING A POSITION
3	ON IT IS IT IS EXTRAORDINARILY DIFFICULT, AS YOU
4	KNOW, TO GET SIGNIFICANT INVESTMENT IN NEW
5	TECHNOLOGY OR NEW PRODUCT AREAS LIKE THIS. AND THE
6	REASON THAT INVESTORS ARE SO RELUCTANT IS THEY
7	REALIZE THAT THE INNOVATOR WILL MAKE ALL THE
8	MISTAKES, WILL HAVE THE LONGEST DELAY FROM THE FOOD
9	AND DRUG ADMINISTRATION, WILL HAVE THE MOST
10	DIFFICULT TIME ESTABLISHING PRICING. ALL OF THOSE
11	THINGS WILL BE DONE BY THE INNOVATOR. AND THEN,
12	BECAUSE THE TIME THAT ELAPSES ON THEIR INTELLECTUAL
13	PROPERTY, THEIR CONCERN IS YOU MAY ONLY HAVE THREE
14	OR FOUR OR FIVE YEARS LEFT ON YOUR PATENTS BEFORE
15	SOMEBODY CAN COME IN AND USE YOUR DATA OR YOUR
16	PATENT EXPIRES AND SOMEBODY CAN COME IN LATER, THEN,
17	AND USE YOUR DATA. BUT THEY WANT A SIGNIFICANT
18	PERIOD OF TIME BEFORE SOMEBODY CAN JUST WALK OVER
19	THERE.
20	SO THERE'S A BROAD COALITION THAT'S IN
21	SUPPORT OF THE ESCHOO BILL. I'M SURE THERE ARE
22	THOSE THAT ARE VERY MUCH BEHIND THE WAXMAN BILL, BUT
23	I HAVEN'T BEEN ABLE TO FIND MANY OF THOSE. I'LL
24	LEAVE IT WITH THAT AND BE HAPPY TO ANSWER QUESTIONS.
25	IS NANCY THERE?

	BARRISTERS' REPORTING SERVICE
1	MS. KOCH: I'M HERE, DUANE.
2	CHAIRMAN KLEIN: SHE IS HERE.
3	MR. ROTH: SO NANCY IS REALLY GOING TO
4	LEAD THIS DISCUSSION ON THE BOARD SIDE, SO SHE MAY
5	HAVE SOMETHING TO ADD TO THAT.
6	MR. GOLDBERG: HAVE WE TAKEN ROLL CALL?
7	MS. KING: THANK YOU SO MUCH, MICHAEL.
8	FOR THE RECORD MICHAEL GOLDBERG HAS JOINED THE
9	MEETING, AND WE NOW HAVE A QUORUM.
10	CHAIRMAN KLEIN: SO LET'S MAKE A FORMAL
11	ROLL CALL TO CONFIRM THAT EVERYONE IS ON.
12	MS. KING: SUSAN BRYANT. MICHAEL
13	GOLDBERG.
14	MR. GOLDBERG: YES, WITH A MEMBER OF THE
15	PUBLIC.
16	MS. KING: BOB KLEIN.
17	CHAIRMAN KLEIN: HERE.
18	MS. KING: CLAIRE POMEROY.
19	DR. POMEROY: HERE.
20	MS. KING: FRANCISCO PRIETO. JEANNIE
21	FONTANA FOR JOHN REED.
22	DR. FONTANA: HERE.
23	MS. KING: DUANE ROTH.
24	DR. ROTH: HERE.
25	MS. KING: JOAN SAMUELSON. JEFF SHEEHY.
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1	MR. SHEEHY: HERE.
2	MS. KING: ART TORRES.
3	MR. TORRES: HERE.
4	MS. KING: AND WE DO HAVE A QUORUM.
5	CHAIRMAN KLEIN: OKAY. THANK YOU. NANCY,
6	WOULD YOU LIKE TO MAKE ANY SPECIFIC COMMENTS. MAYBE
7	JAMES COULD MOVE THAT SPEAKER OVER TOWARDS YOU.
8	MS. KOCH: DUANE WAS PERFECTLY ACCURATE.
9	I THOUGHT I MIGHT JUST BE ABLE TO GIVE A LITTLE BIT
10	OF CONTEXT. THE FIRST IS, AS MANY OF YOU KNOW, THIS
11	IS A SUBJECT THAT HAS BEEN AROUND IN THE HALLS OF
12	WASHINGTON FOR SOME TIME, ESPECIALLY INTENSIVELY IN
13	THE LAST YEAR OR TWO.
14	THE INFORMATION WE'RE GETTING FROM OUR
15	COLLEAGUES IN WASHINGTON IS THAT THINGS ARE MORE
16	LIKELY TO ACTUALLY COME TO FRUITION THIS YEAR, THAT
17	THERE IS VERY LIKELY TO BE MOVEMENT HERE BECAUSE OF
18	THE CHANGE IN THE WHITE HOUSE, BECAUSE OF THE CHANGE
19	TO A DEMOCRAT MAJORITY, AND BECAUSE THE BILLS THAT
20	HAVE BEEN INTRODUCED SO FAR, THAT IS, BY ESCHOO AND
21	BY WAXMAN, BOTH HAVE SORT OF COMPROMISED FORWARD
22	FASTER IN A WAY THAT HASN'T HAPPENED IN THE PAST.
23	SO THEY'RE STARTING FROM A PLACE THAT'S
24	MORE SIMILAR THAN THEY HAD BEEN STARTING BEFORE.
25	THERE'S POLITICAL REASONS WHY IT SHOULD MOVE
	0

	DARRISTERS REPORTING SERVICE
1	QUICKLY, AND THE OBAMA ADMINISTRATION HAS ACTUALLY
2	COUNTED IN ITS FISCAL YEAR 2010 BUDGET ON THIS
3	LEGISLATION GOING THROUGH AND THE COUNTRY BEGINNING
4	TO EXACT VERY SIGNIFICANT SAVINGS TO THE TUNE OF
5	SOMETHING LIKE 9.2 OR \$10 BILLION OVER A PERIOD OF
6	TEN YEARS.
7	SO THIS IS GOING TO GET A LOT OF FOCUS AND
8	ESPECIALLY A LOT OF FOCUS IN THE NEXT 30 DAYS, WHICH
9	IS TO SAY IF THE ICOC, AFTER CONSIDERATION, ISN'T
10	GOING TO DO SOMETHING, THEY MIGHT DO IT NOW. THAT'S
11	WHY DUANE IS BRINGING THIS TO THE COMMITTEE AND THEN
12	ON TO THE BOARD.
13	CHAIRMAN KLEIN: OKAY.
14	MS. KOCH: THE ONLY OTHER THING I'D SAY IS
15	THAT DUANE IS ABSOLUTELY RIGHT, THAT THE MAIN FOCUS
16	HERE IS THE PERIOD DURING WHICH THE INNOVATOR WILL
17	HAVE EXCLUSIVE USE OF THIS DATA; THAT IS, A PERIOD
18	OF TIME BEFORE WHICH ANYONE CAN MOVE ON THAT DATA.
19	THERE ARE OTHER SUBTLE DIFFERENCES; AND WHEN YOU
20	REALLY DIG DOWN INTO THE WEEDS, WHICH IS WHAT
21	LAWYERS ARE PAID TO DO YOU ARE PAYING, BOB THE
22	DIFFERENCE IN TIMING MAY ACTUALLY BE EVEN MORE
23	SIGNIFICANT BETWEEN ESCHOO AND WAXMAN THAN THE SORT
24	OF 12/5 SPLIT THAT DUANE SAID BECAUSE IN THE ESCHOO

BILL, THE FDA IS NOT REALLY ALLOWED TO APPROVE ANY

25

1	BIOSIMILAR PRODUCT UNTIL IT ISSUES FORMAL GUIDANCE
2	WITH REGARD TO THAT SPECIFIC PRODUCT CLASS OF DRUG.
3	AND THE PROCESS OF ISSUING GUIDANCE REQUIRES PUBLIC
4	HEARINGS AND A DETAILED PROCESS, WHICH IN AND OF
5	ITSELF CAN BE TIME-CONSUMING.
6	AND THEN ESCHOO SPECIFICALLY ALLOWS THE
7	FDA TO SAY, NO, AT THIS POINT, GIVEN THE SCIENCE, NO
8	BIOSIMILARS ARE ALLOWED WHATSOEVER. SO THAT HER
9	THRUST IS TOWARD CONSERVATISM AND MOVING SLOWLY, AND
LO	WAXMAN'S THRUST IS MUCH MORE TOWARD WE'RE GOING TO
L1	GIVE THE FDA DISCRETION, BUT WE WANT TO GET THIS
L2	GOING AND MOVE QUICKLY.
L3	MR. TORRES: I WANTED TO CONGRATULATE
L4	DUANE BECAUSE, DUANE, YOU'VE DONE AN EXCELLENT JOB
L5	IN UPDATING, ESPECIALLY ME, IN AN AREA THAT I WAS
L6	NOT VERY SIMILAR WITH. AND I SUPPORT DUANE'S
L7	POSITION ON THIS FOR ONE IMPORTANT REASON. AT THE
L8	END OF THE DAY, AS NANCY SAID, WE'RE GOING TO GET TO
L9	A CONFERENCE COMMITTEE. AND AT THE END OF THE DAY,
20	WE'RE GOING TO GET TO THE SENATE; BUT I THINK AT THE
21	END OF THE DAY, WE HAVE TO BE TRUE TO THE PEOPLE
22	THAT WE WANT TO ENCOURAGE TO EXIST IN THIS STATE,
23	WHICH ARE THESE COMPANIES. AND MARKET EXCLUSIVITY
24	IS AN INTEGRAL OF THAT FUTURE AND THAT VISION, AS
25	DUANE HAS SAID, AND YOU AND I HAVE TALKED ABOUT IT

1	AS WELL, BOB.
2	SO IF THIS BOARD MOVES TOWARD A POSITION,
3	I WOULD PREFER THAT WE SUPPORT THE ESCHOO BILL IF WE
4	CAN DO THAT, IF THERE ARE VOTES TO DO THAT, BECAUSE
5	AT THE END OF THE DAY, HENRY WILL BE COMING TO US TO
6	WORK OUT A COMPROMISE ANYWAY. AND AT THE END OF THE
7	DAY, THERE'S GOING TO BE, BECAUSE OF THE INTENSITY
8	OF THIS DEBATE, THERE'S GOING TO BE A CONFERENCE
9	COMMITTEE OF BOTH SENATE AND HOUSE MEMBERS, I WOULD
10	THINK. AT THAT POINT EVERYBODY WILL COME TOGETHER,
11	BUT AT LEAST WE'VE TAKEN A STAND WHERE WE THINK WE
12	NEED TO BE FROM OUR POSITION AND PROTECTING THE
13	INTEGRITY OF COMPANIES THAT REALLY NEED HELP.
14	CHAIRMAN KLEIN: THANK YOU VERY MUCH, ART.
15	LET ME ASK DID WE INVITE THE LEGISLATORS TO HAVE
16	REPRESENTATIVES AND COMMENTS?
17	MS. KING: WE DID INVITE THEM TO BE BOTH
18	ON THIS CALL AND ALSO TO BE AT THE MEETING. I
19	UNDERSTAND THAT THERE'S MORE POTENTIAL INTEREST FOR
20	THEM TO ACTUALLY COME TO THE BOARD MEETING, AND IT
21	MAY NOT ACTUALLY BE THE MEMBERS BECAUSE THEY'LL BE
22	IN WASHINGTON, BUT THEY MAY HAVE REPRESENTATIVES
23	THAT COME TO THE MEETING IN L.A.
24	CHAIRMAN KLEIN: OKAY.
25	MS. KING: WE INVITED THEM A COUPLE WEEKS

1	AGO.
2	CHAIRMAN KLEIN: THAT WAS MY
3	UNDERSTANDING. JUST WANTED TO CONFIRM IT FOR THE
4	PUBLIC AND FOR THE MEMBERS.
5	MS. KING: WE ALSO INVITED THEM TO INVITE
6	GROUPS, OTHER THAN THEMSELVES AND THEIR STAFF
7	MEMBERS, TO INVITE GROUPS THAT WERE IN SUPPORT OF
8	THEIR OWN BILLS.
9	CHAIRMAN KLEIN: ALL RIGHT. SO ADDITIONAL
10	COMMENTS FROM MEMBERS?
11	DR. FONTANA: I JUST HAVE A CLARIFICATION.
12	THE REASON WHY WE'RE MAKING A POSITION, THAT CIRM IS
13	MAKING A POSITION ON THESE TWO BILLS IS?
14	CHAIRMAN KLEIN: IS BECAUSE OF THE
15	POTENTIAL IMPORTANCE OF THE LONGER PERIOD OF
16	EXCLUSIVITY TO BE ABLE TO GET CAPITAL IN THIS NEW
17	AREA OF RELATIVELY HIGH RISK OF CELLULAR THERAPIES
18	AND STEM CELL-DERIVED THERAPIES.
19	DR. FONTANA: STEM CELL, ANY THERAPEUTICS
20	DERIVED FROM STEM CELLS WILL FALL UNDER THIS
21	LEGISLATION?
22	MR. ROTH: YES.
23	MS. KOCH: YES. DEFINITIONS OF BIOLOGICS
24	ARE CURRENTLY DEFINED, AND AS WE EXPECT THAT WILL
25	BE. THE ANSWER TO THAT IS YES.

1	CHAIRMAN KLEIN: SO I WOULD LIKE NANCY AND
2	DUANE, AS WE GO FORWARD ON THIS, IF WE TAKE AN
3	ACTION TODAY, AT THE BOARD MEETING WE HAVE SOME
4	ADDITIONAL INFORMATION ON SUBPOINT 3 OF THE ESCHOO
5	BILL THAT DEALS WITH THE CRITERIA FOR MEETING A
6	BIOSIMILAR AS TO THE ISSUE OF IDENTICAL APPLICATIONS
7	AS IN A STUDY SESSION THAT THE STAFF HAD LAST WEEK.
8	ALAN IS FAMILIAR WITH THAT, WITH THAT SUMMARY AS TO
9	THOSE CRITERIA, AND I THINK IT WOULD BE IMPORTANT TO
10	GET DOWN INTO THE DEEP WEEDS ON THIS ONE. AND TO
11	THE EXTENT THAT WE HAVE A POLICY APPROVAL GOING
12	FORWARD, WE HAVE A COMMENTARY POTENTIALLY ABOUT THAT
13	SUBSECTION, WHICH WE NEED SOME MORE INFORMATION ON.
14	SO ARE THERE PUBLIC COMMENTS ON THESE TWO
15	BILLS? HEARING NO PUBLIC COMMENT, IS THERE A MOTION
16	FOR APPROVAL OF EITHER BILL, ENDORSEMENT?
17	MR. GOLDBERG: I'D LIKE TO MAKE A MOTION
18	TO ENDORSE THE ESCHOO BILL.
19	CHAIRMAN KLEIN: ALL RIGHT. IS THERE A
20	SECOND?
21	MR. TORRES: SECOND.
22	DR. FONTANA: SECOND THAT.
23	CHAIRMAN KLEIN: SECOND BY BOTH JEANNIE
24	FONTANA AND ART TORRES. SO DISCUSSION ON THE
25	MOTION? HEARING NO DISCUSSION ON THE MOTION, ANY

I	1
1	PUBLIC COMMENT ON THE MOTION? NO PUBLIC COMMENT ON
2	THE MOTION, CALL THE ROLL CALL, PLEASE.
3	MS. KING: MICHAEL GOLDBERG.
4	MR. GOLDBERG: YES.
5	MS. KING: BOB KLEIN.
6	CHAIRMAN KLEIN: YES.
7	MS. KING: CLAIRE POMEROY.
8	DR. POMEROY: YES.
9	MS. KING: JEANNIE FONTANA.
10	DR. FONTANA: YES.
11	MS. KING: DUANE ROTH.
12	DR. ROTH: YES.
13	MS. KING: JEFF SHEEHY.
14	MR. SHEEHY: I'M GOING TO ABSTAIN.
15	MS. KING: ART TORRES.
16	MR. TORRES: AYE.
17	MS. KING: AND FOR THE RECORD THAT MOTION
18	CARRIES WITH ONE ABSTENTION.
19	CHAIRMAN KLEIN: ALL RIGHT. THANK YOU
20	AND, AGAIN, HOPEFULLY WE WILL HAVE REPRESENTATIVES
21	OF BOTH LEGISLATORS AT THE BOARD MEETING TO COMMENT
22	ON THIS. SO THIS IS A RECOMMENDATION AT THIS POINT
23	SUBJECT TO ADDITIONAL INFORMATION AND THE SPECIFIC
24	DETAIL REPORT THAT I'VE ASKED ON ONE SUBSECTION OF
25	COMPARISON.
	14

1	THE NEXT ITEM ON THE AGENDA IS THE NIH
2	DRAFT GUIDELINES. AND WHAT I'D LIKE TO DO IS, FIRST
3	OF ALL, START WITH, DR. TROUNSON, WOULD YOU LIKE TO
4	JUST GIVE A SUMMARY OF THE KIND OF RECEPTION THAT WE
5	GOT IN WASHINGTON, D.C., RELATED TO NIH'S OPENNESS
6	TO THE COMMENTS PROCESS? AND THEN I'M GOING TO ASK
7	GEOFF LOMAX TO GIVE US A REPORT.
8	DR. TROUNSON: THANKS, BOB. BOB KLEIN AND
9	I HAD A MEETING WITH THE ACTING DIRECTOR OF NIH AND
10	STORY LANDIS, WHO HEADS THE STEM CELL INITIATIVE
11	CURRENTLY FOR THEM. AND WE WERE VERY WELL RECEIVED
12	FOR THE COMMENTS THAT WE MADE.
13	THERE WAS A CONCERN BY NIH THAT PEOPLE HAD
14	REACTED TOO QUICKLY TO THEIR DRAFT GUIDELINES, AND
15	WE WERE ABLE TO GET SOME EXPLANATION OF SOME OF THE
16	ISSUES THAT ARE DIRECTLY AFFECTING THEM. BUT THEY
17	CONGRATULATED US ON TAKING A PRODUCTIVE INITIAL
18	STANCE ON IT AND GAVE US SOME INSIGHTS INTO THE WAY
19	WE COULD PREPARE A FORMAL DOCUMENT THAT WOULD BE
20	EFFECTIVE OR WOULD BE HELPFUL IN ADDRESSING THE
21	ISSUES THAT WE HAD SOME CONCERNS ABOUT.
22	SO WE'RE IN THE PROCESS OF COMBINING THE
23	NOTES THAT BOB AND I TOOK, AND WE'VE GOT THOSE NOTES
24	TO GEOFF LOMAX AND TO ELONA BAUM, WHO'S THE NEW
25	GENERAL COUNSEL. AND WE WOULD LIKE THEM TO PREPARE

1	A DOCUMENT ALONG THE KIND OF GUIDELINES OR THE
2	SUGGESTIONS THAT WERE MADE BY NIH.
3	AND I THINK OVERALL IS A VIEW THAT NIH
4	NEEDS TO BE ABLE TO ACHIEVE EVERYTHING THAT THE
5	INDUSTRY REALLY, THAT IS THE RESEARCHERS, REALLY
6	NEED, BUT THEY WILL HAVE TO DO THAT WITH SOME
7	COMPROMISES. ONE OF THOSE WHICH IS NOT WELL
8	RECOGNIZED IS THE BUSH ETHICS COMMITTEE IS STILL IN
9	PLACE. AND THAT WOULD ESSENTIALLY PREVENT ANY WORK
10	GOING ON ON EMBRYONIC STEM CELL LINES DERIVED FROM
11	PARTHENOGENETICS OR NUCLEAR TRANSFER AT THIS POINT.
12	I THINK THERE'S AN OPPORTUNITY TO REVISE THAT WHEN
13	THAT ETHICS COMMITTEE ACTUALLY DISSOLVES. I THINK
14	THAT WAS IN SEPTEMBER.
15	I THINK SOME OF THE OTHER ISSUES WE WERE
16	HELPED IN THINKING ABOUT PREPARING THAT, BUT IT WAS
17	VERY CLEAR, IF WE'RE ABLE TO GET STRONG SUPPORT FROM
18	THE SCIENTIFIC COMMUNITY IN TERMS OF NUMBERS OF
19	SUPPORTIVE APPLICATIONS PARTICULARLY OR LETTERS TO
20	THE NIH, THAT WOULD BE VERY EFFECTIVE. AND THEIR
21	RECOMMENDATION WAS TO BE VERY CLEAR ABOUT THE IMPACT
22	THAT THE REGULATIONS WOULD HAVE IN THE FUTURE.
23	SO I THINK THAT WAS A VERY REWARDING
24	MEETING, I THINK, WITH A LOT OF SUPPORT FROM NIH,
25	AND I THINK WE GOT A LOT FROM THEM AS A RESULT.

CHAIRMAN KLEIN: SO JUST TO SUPPLEMENT
ALAN'S COMMENTS, THE INSIGHTS ALAN IS REFERRING TO
IS REALLY OF PROCESS. AND AFTER A GOOD SUBSTANTIVE
DISCUSSION ON THE REASONS THAT GRANDFATHERING NEEDED
TO REACH, NOT JUST THE PRESIDENTIAL LINES, WHICH THE
NEW STANDARDS, IN FACT, KNOCK OUT MANY OF THOSE, BUT
IN TERMS OF REACHING THE STATE LINES THAT HAVE BEEN
APPROVED, STATES AND UNIVERSITIES LINES HAVE BEEN
APPROVED, BUT ALSO INTERNATIONAL LINES, THAT THE
FEEDBACK WAS THAT THE SCIENTIFIC JUSTIFICATIONS WE
WERE GIVEN WERE APT TO BE WELL RECEIVED BECAUSE OF
THE NECESSITY OF CONSERVING THE TREMENDOUS VALUE OF
THE RESEARCH THAT'S BEEN DONE ON THAT SCOPE OF
LINES.
SO ONE OF THE SPECIFIC AREAS THAT REALLY

SO ONE OF THE SPECIFIC AREAS THAT REALLY
HADN'T BEEN BROUGHT UP TO THEM PREVIOUSLY WAS THE
VALUE OF THESE INTERNATIONAL LINES. WE POINTED OUT
THAT WHILE WE ARE IN BILATERAL AGREEMENTS WITH FIVE
DIFFERENT COUNTRIES, WHETHER THE SPECIFIC WORK BY
EXAMPLE ON RETINAL PIGMENT EPITHELIAL CELLS AT THE
UNITED KINGDOM ARE BASED UPON UK STEM CELL BANK OR A
HOST OF MANY OTHER AREAS OF DISEASE BEING STUDIED ON
DISEASE-SPECIFIC LINES IN LEGITIMATELY, PROPERLY
TRANSPARENTLY CREATED STEM CELL BANKS AND OTHER
INTERNATIONALLY RESPECTED LINES MUST BE PRESERVED IN

ORDER TO SUSTAIN INTERNATIONAL COLLABORATIONS THAT
ARE SO IMPORTANT IN MOVING THIS RESEARCH FORWARD.
WITH THAT BACKGROUND, I'D LIKE TO GET
GEOFF LOMAX TO GIVE US BY SECTION WALK US THROUGH
THE HIGH POINTS OF A VERY WELL-CONSTRUCTED REPORT
THAT HE'S PUT TOGETHER ON THIS ISSUE.
DR. LOMAX: THANK YOU, BOB. WHAT WE'VE
DONE YOU WILL SEE THERE'S A DRAFT DOCUMENT THAT WE
PUT TOGETHER THAT REALLY REFLECTS THE WORK OF LAST
WEEK, WHICH WAS OUR, I THINK, OUR FIRST SORT OF CUT
THROUGH BOTH THE GUIDELINES AND I THINK, MOST
IMPORTANTLY, AS WE TALKED ABOUT A FORMAL EVALUATION
PROCESS. I THINK ONE OF THE HIGHLIGHTS OF THAT
PROCESS WAS A SERIES OF KEY INFORMANT INTERVIEWS
ACROSS THE STATE AND ACROSS THE COUNTRY.
I THINK TO HIGHLIGHT WHAT WE DID IN THE
FRONT END OF THAT DOCUMENT, I THINK THERE'S SORT OF
THREE LEVELS TO IT. THE FIRST LEVEL IS KIND OF A
HIGH LEVEL KIND OF A SCOPING AND A CONCEPTUAL
OVERVIEW, WHAT'S IN, WHAT'S OUT. WE COULD HAVE DONE
THAT, WHICH WE ALL ARE AWARE THAT THE NIH POLICY
ALLOWS SOME MATERIALS TO BE IN, SOME MATERIALS TO BE
OUT. AND I SORT OF SEE THAT AS A HIGH LEVEL POLICY
ISSUE WHERE WE KIND OF LAID OUT SOME OF THE
OVERARCHING CONSTRAINTS THAT NIH IS WORKING UNDER
18

1	AND TO TRY GIVE EVERYONE A SENSE OF EXACTLY WHAT THE
2	LIMITATIONS ARE. FOR EXAMPLE, WE HAVE THE
3	DICKEY-WICKER LANGUAGE IN THERE, AND WE HAVE
4	LANGUAGE FROM THE EXECUTIVE ORDER. AND WE'VE
5	HIGHLIGHTED WHERE THERE WAS DISCRETION USED BY THE
6	NIH AND OBVIOUSLY WOULD LOOK FORWARD TO THIS
7	COMMITTEE AND THE ICOC TO SORT OF COME TO AN OPINION
8	ON THE USE OF THAT DISCRETION. AND THAT WOULD HELP
9	FORMULATE OUR RESPONSE AT THE SORT OF HIGH LEVEL
10	CONCEPTUAL LEVEL.
11	WHERE I THINK WE SPENT MOST OF OUR TIME
12	WHERE WE THINK WE CAN BE OF MOST BENEFIT TO THE
13	PROCESS IS SORT OF MORE AT THE MORE DETAILED LEVEL
14	OF THESE GUIDELINES IN TERMS OF POSING VERY FOCUSED
15	FEEDBACK BACK TO THE NIH, PARTICULARLY FOR AREAS
16	WHERE WE THINK WE NEED CLARIFICATION AND TO
17	HIGHLIGHT VERY SPECIFIC POLICY IMPACTS WHICH HAVE
18	BEARING ON THE SCIENCE.
19	AND CALL YOUR ATTENTION TO ATTACHMENT B,
20	WHICH IS THE TABLE WHERE WE'VE GONE THROUGH AND
21	INITIATED A SORT OF POINT-BY-POINT ANALYSIS ONLY OF
22	THOSE POINTS WHERE WE THINK THERE IS THE BASIS FOR
23	COMMENTS. WE HAVEN'T TRIED TO PUT EVERY SINGLE
24	POINT OF THE GUIDELINES INTO THIS TABLE, BUT WE'VE
25	STARTED TO FORMULATE AN ANALYSIS WHICH I THINK WILL

1	INFORM WHAT I'M CALLING NOW THE SECOND LEVEL, WHICH
2	IS THE MORE NUANCED FEEDBACK TO NIH ABOUT WHERE WE
3	MIGHT LOOK FOR CLARIFICATION OR ABOUT WHERE THERE
4	MAY BE IMPACTS WHICH ARE OF CONCERN TO THE
5	SCIENTIFIC COMMUNITY. BOB, YOU SORT OF TOUCHED ON
6	THAT.
7	I THINK ONE OF THE BIG HIGHLIGHTS IS THE
8	POTENTIAL FOR THIS POLICY TO TAKE MATERIALS OFF THE
9	TABLE THAT ARE SCIENTIFICALLY IMPORTANT. I THINK
10	THERE'S A BROAD AND CONSISTENT CONCERN ACROSS THE
11	COMMUNITY THAT THAT IMPACT IS REAL. AND OVER THE
12	WEEKEND, WE GOT CLARIFICATION FROM A NUMBER OF
13	INSTITUTIONS THAT HAVE THINGS LIKE CONSENT FORMS AT
14	THEIR DISPOSAL TO SAY, YES, A NUMBER OF MATERIALS OF
15	SCIENTIFIC RELEVANCE WILL NOT PASS THE BAR HERE. SO
16	WE NEED SOME FEEDBACK ABOUT THE IMPORTANCE OF THOSE
17	MATERIALS.
18	CHAIRMAN KLEIN: AND AT THIS MOMENT, SO
19	THAT WE MAKE SURE WE MAINTAIN A QUORUM FOR THIS
20	VOTE, CLAIRE, YOU STILL WITH US?
21	DR. POMEROY: YES, I AM FOR A FEW MORE
22	MINUTES.
23	CHAIRMAN KLEIN: LET ME ASK THIS. I THINK
24	IT WOULD BE WELL ADVISED IF, AS I'VE RECOMMENDED
25	HERE IN THE MATERIALS WE'VE SENT OUT, THAT WE CREATE
	20

1	A TASK FORCE THAT WORKS WITH DR. TROUNSON, WORKS
2	WITH GEOFF LOMAX, HAS THE ADVICE OF THE INTERSTATE
3	ALLIANCE ON MEDICAL AND ETHICAL STANDARDS, AND MAJOR
4	INSTITUTIONS THROUGHOUT THE STATE TO IMMEDIATELY
5	COMMENCE A PROCESS, INCLUDING A PUBLIC HEARING OR
6	HEARINGS, WHERE WE REALLY DO A THOUGHTFUL JOB OF
7	INTEGRATING COMMENTS, INCLUDING THOSE OF THE PUBLIC,
8	FOR OUR COMMENTS TO WASHINGTON.
9	AND I WILL INDICATE TOO THAT IT IS
10	SUGGESTED THAT IT IS VERY HELPFUL IN WASHINGTON TO
11	DEVELOP WITHIN REGIONS AT LEAST A CONSISTENT
12	TEMPLATE OF COMMENTS WITH A HIGH CONSENSUS SO YOU
13	HAVE HUNDREDS, IF NOT THOUSANDS OF LETTERS THAT
14	FOLLOW THE SAME TEMPLATE. SO TO THE EXTENT WE CAN
15	DEVELOP A GOOD CONSENSUS THAT FOLLOWS A TEMPLATE
16	THAT OTHERS CAN PICK UP, THERE WILL BE LETTERS
17	COUNTED IN THE PRESS. ACCORDING TO THE NIH, THE
18	PRESS VIEW OF THIS AND EVEN UP TO THE WHITE HOUSE
19	LEVEL OFTEN FOCUSES ON HOW MANY INDIVIDUALS OR
20	SCIENTIFIC AUTHORITIES AGREED ON THE SAME MESSAGE.
21	SO A TASK FORCE COULD CERTAINLY HELP DO
22	THAT. AT THIS POINT, I WOULD ASK IS THERE A MOTION
23	TO HAVE A TASK FORCE WHILE WE'RE GOING FORWARD WITH
24	THIS CONSIDERATION? AND THAT TASK FORCE MIGHT,
25	SUBJECT TO THE BOARD, RESULT IN A BOARD TELEPHONIC

1	MEETING WITHIN THE 30-DAY PERIOD TO APPROVE THE
2	FINAL REPORT OF THE TASK FORCE.
3	DR. FONTANA: I MOVE THAT.
4	CHAIRMAN KLEIN: IS THERE A SECOND?
5	MR. TORRES: SECOND.
6	CHAIRMAN KLEIN: SECOND BY ART TORRES. IS
7	THERE DISCUSSION ON THAT?
8	DR. POMEROY: BOB, CAN YOU JUST CLARIFY
9	THE DELIVERABLE FROM THE TASK FORCE?
10	CHAIRMAN KLEIN: THE DELIVERABLE FROM THE
11	TASK FORCE WOULD BE A SPECIFIC SET OF COMMENTS ON
12	THE NIH PROPOSED MEDICAL AND ETHICAL STANDARDS ON
13	EMBRYONIC STEM CELL RESEARCH.
14	DR. POMEROY: BY SOME DATE?
15	CHAIRMAN KLEIN: WITHIN THE 30-DAY COMMENT
16	PERIOD WITH A TELEPHONIC BOARD CALL TO APPROVE THAT
17	DELIVERABLE.
18	DR. POMEROY: SOUNDS GOOD.
19	DR. TROUNSON: WE JUST NEED IT DONE IN
20	SUFFICIENT TIME THAT WE CAN ENCOURAGE OUR COLLEAGUES
21	TO SUPPORT THE MATERIAL THAT WE'RE PUTTING FORWARD
22	SO THAT WE GET A STRONG SUPPORT FROM THE SCIENTIFIC
23	COMMUNITY REALLY ACROSS THE STATES.
24	CHAIRMAN KLEIN: AND SO I WOULD HOPE THAT
25	THE TASK FORCE CAN QUICKLY DEVELOP A DRAFT THAT IT
	22

1	CIRCULATES FOR COMMENT WHILE THE PUBLIC PROCESS IS
2	PROCEEDING.
3	ADDITIONAL COMMENTS? GEOFF.
4	DR. LOMAX: I THINK THE OTHER THING, IF IT
5	FALLS WITHIN THIS MOTION AND IS APPROPRIATE, I THINK
6	THE COMMUNITY IS LOOKING TOWARDS OUR SUBSTANTIVE
7	ANALYSIS TO HELP INFORM THEIR OWN COMMENTS. IF
8	WE'RE ABLE TO, AT THE WILL OF THE COMMITTEE, PROVIDE
9	OUR SUBSTANTIVE BREAKDOWN, THINGS LIKE APPENDIX B,
10	ON AN ONGOING BASIS, THE MEMBERS OF THE PUBLIC, IF
11	THAT'S APPROPRIATE, WE CAN CONTINUE TO DO THAT. I
12	KNOW THE STAKEHOLDER COMMUNITY IS LOOKING FOR US FOR
13	THAT LEVEL OF ANALYSIS, THE RIGOR WE CAN BRING TO
14	THE PROCESS.
15	CHAIRMAN KLEIN: I THINK THE PUBLIC AND
16	THE STAKEHOLDER COMMUNITY ALL BENEFIT BY THE
17	TREMENDOUS WORK YOU'VE DONE WITH INTERSTATE
18	ALLIANCE. SO ADDITIONAL IS THERE PUBLIC COMMENT?
19	HEARING NONE, COULD I HAVE A ROLL CALL, PLEASE.
20	MS. KING: MICHAEL GOLDBERG.
21	MR. GOLDBERG: YES.
22	MS. KING: BOB KLEIN.
23	CHAIRMAN KLEIN: YES.
24	MS. KING: CLAIRE POMEROY.
25	DR. POMEROY: YES.
	23
	LJ

1	MS. KING: JEANNIE FONTANA.
2	DR. FONTANA: YES.
3	MS. KING: DUANE ROTH.
4	DR. ROTH: YES.
5	MS. KING: JEFF SHEEHY.
6	MR. SHEEHY: YES.
7	MS. KING: ART TORRES.
8	MR. TORRES: AYE.
9	MS. KING: AND THAT MOTION CARRIES. AND I
10	JUST WANTED TO CHECK VERY QUICKLY. IS THERE ANYONE
11	ON THE SUBCOMMITTEE THAT I'M NOT CALLING THAT HAS
12	JOINED THE CALL? NO.
13	CHAIRMAN KLEIN: THANK YOU. SO, GEOFF,
14	COULD YOU PROCEED TO THE NEXT LEVEL OF DEPTH YOU
15	HAVE IN YOUR COMMENTS?
16	DR. LOMAX: AGAIN, TO SUMMARIZE, WE'VE
17	TALKED ABOUT THIS. WE'VE DESCRIBED THE SCOPE.
18	WE'VE GIVEN A VERY SORT OF DETAILED BREAKDOWN IN
19	APPENDIX B.
20	AND THEN FINALLY, I JUST WANT TO HIGHLIGHT
21	SOME OF THE NEXT STEPS, THE SORT OF THINGS I THINK
22	THAT WILL HELP NIH SORT OF NAVIGATE IN THE LONGER
23	RUN. TWO ITEMS, FIRST, THERE'S AN ATTACHMENT B,
24	WHICH IS SORT OF A DOCUMENT SORT OF HIGHLIGHTING
25	WAYS IN WHICH WE CAN BRING THE RESEARCH COMMUNITY IN

1	TO HELP VALIDATE STEM CELL LINES. I THINK THERE'S A
2	GREAT CONCERN OUT THERE THAT IF THERE'S NOT A
3	REGISTRY OR SOME TYPE OF MECHANISM FOR REGISTRATION
4	OF LINES, THAT WILL POSE A GREAT CHALLENGE TO THE
5	FIELD, PARTICULARLY IF WE START SEEING INSTITUTIONS
6	TAKING DIFFERENT SIDES ON PARTICULAR CELL LINES,
7	WHETHER THEY'RE IN OR OUT.
8	WE TRIED TO POINT TO SOME OF THE
9	INNOVATIVE THINKING WE'VE DONE BOTH HERE AT CIRM AND
10	WITHIN THE INTERSTATE ALLIANCE WHICH CONSTITUTES THE
11	STATE STEM CELL PROGRAMS AND INTERNATIONAL PARTNERS.
12	SO IN ADDITION TO COMMENTING ON THE GUIDELINES
13	SPECIFICALLY, MY UNDERSTANDING FROM NIH IS THEY
14	WOULD GREATLY BENEFIT FROM OUR EXPERIENCE IN THIS
15	WORK, TRYING TO POINT TO PATHWAYS FOR THE FUTURE IN
16	WHICH WE CAN REALLY FACILITATE THE FLOW OF MATERIALS
17	INTO THE RESEARCH STREAM.
18	SO I WOULD SUGGEST THERE'S AN OPPORTUNITY
19	FOR A THIRD LEVEL HERE, WHICH IS TO MOVE BEYOND THE
20	SPECIFIC COMMENTS AND HIGHLIGHT OPPORTUNITIES FOR
21	THE FUTURE THAT WILL REALLY MOVE THE FIELD FORWARD
22	IN A PRODUCTIVE WAY. SO THAT IS REALLY REFLECTED AS
23	ATTACHMENT C AND THE ONGOING COMMUNICATION WITH
24	NATIONAL PARTNERS, WHICH WE HAVE A MEETING SCHEDULED
25	FOR MAY 5TH IN WASHINGTON WITH THE INTERSTATE GROUP,

1	AND WE'LL DO SOME BRAINSTORMING THERE AS WELL AND
2	MAYBE HIGHLIGHT SOME OTHER OPPORTUNITIES AND BRING
3	THAT BACK AS FEEDBACK IN THE PROCESS.
4	CHAIRMAN KLEIN: ALL RIGHT. AND MY
5	UNDERSTANDING AS WELL FROM THE DISCUSSION WITH IRV
6	WEISSMAN OVER THE WEEKEND IS THAT OBAMA IS GOING TO
7	ADDRESS THE NATIONAL ACADEMY THIS WEEK POTENTIALLY
8	ON THIS SUBJECT. HE DID THIS MORNING.
9	MR. ROTH: I JUST LOOKED AT IT. I CAN
10	TELL YOU IF THERE'S ANYTHING IN IT.
11	CHAIRMAN KLEIN: IT'S GOING TO BE A
12	SUBJECT OF SIGNIFICANT FOCUS.
13	ALL RIGHT. ANY ADDITIONAL COMMENTS WE'D
14	LIKE TO MAKE DURING THIS MEETING?
15	MR. JENSEN: PUBLIC COMMENT.
16	CHAIRMAN KLEIN: PUBLIC COMMENT.
17	MR. JENSEN: THIS IS DAVID JENSEN FROM THE
18	CALIFORNIA STEM CELL REPORT. COULD GEOFF SEND OR
19	E-MAIL ME THE COPY OF THE DOCUMENTS HE REFERS TO,
20	PLEASE?
21	CHAIRMAN KLEIN: GEOFF, COULD YOU SEND
22	MS. KING: I MIGHT BE ABLE TO HELP.
23	DAVID, THIS IS MELISSA KING. AND ARE YOU TALKING
24	ABOUT THE DOCUMENTS THAT WE'VE BEEN LOOKING AT
25	DURING THE MEETING?

1	MR. JENSEN: THE DOCUMENT THAT GEOFF LOMAX
2	REFERRED TO.
3	MS. KING: WHICH IS ONE OF OUR
4	ATTACHMENTS. I WOULD BE HAPPY TO E-MAIL ALL OF
5	THOSE TO YOU. ALSO, I'M HOPING THAT THEY WILL BE
6	POSTED ON THE WEBSITE THIS MORNING. I JUST
7	UNFORTUNATELY DIDN'T GET THEM UNTIL THE AFTERNOON
8	FOR VARIOUS REASONS ON FRIDAY. AND BECAUSE WE WORK
9	WITH THE STATE DATA CENTER, I COULDN'T GET THEM
10	POSTED. I REALLY APOLOGIZE FOR THAT.
11	MR. JENSEN: THANK YOU. I APPRECIATE
12	WHATEVER YOU CAN DO.
13	DR. LOMAX: WE'LL GET THEM TO YOU ONE WAY
14	OR THE OTHER. THIS HAS BEEN KIND OF REAL-TIME
15	PROCESSING, AND MELISSA HAS BEEN DOING EVERYTHING
16	SHE CAN, BUT WE RAN INTO A TIME CRUNCH.
17	MR. JENSEN: THANK YOU.
18	CHAIRMAN KLEIN: OKAY.
19	MR. ROTH: BOB, I DON'T SEE ANYTHING ON
20	HERE ABOUT NIH IN HIS SPEECH. I THINK SWINE FLU
21	TOOK IT OFF THE COVER.
22	CHAIRMAN KLEIN: I SEE. TRUMPED THE
23	PROCESS. OKAY. I DO KNOW THAT HE WAS GOING TO TALK
24	WITH SEVERAL SCIENTISTS IN TERMS OF THEIR COMMENTS
25	ON THIS, BUT HOPEFULLY THE COUNTRY AND THE WORLD
	27

1	GETS THROUGH THIS SWINE FLU ISSUE WHILE WE PROCEED
2	ON THE LONGER TERM RESEARCH AGENDAS.
3	ANY ADDITIONAL COMMENTS? HEARING NONE,
4	ADJOURN THIS MEETING. AND WE THANK YOU VERY MUCH
5	FOR GETTING UP EARLY.
6	MS. KING: THANKS, EVERYBODY.
7	(THE MEETING WAS THEN ADJOURNED AT
8	08:06 A.M)
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REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE TELEPHONIC PROCEEDINGS BEFORE THE LEGISLATIVE SUBCOMMITTEE TO THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR ON MONDAY, APRIL 27, 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.

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