

BEFORE THE
SCIENTIFIC AND MEDICAL ACCOUNTABILITY STANDARDS
WORKING GROUP
TO THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
ORGANIZED PURSUANT TO THE
CALIFORNIA STEM CELL RESEARCH AND CURES ACT
REGULAR MEETING

LOCATION: THE CALIFORNIA INSTITUTE FOR
REGENERATIVE MEDICINE
210 KING STREET
SAN FRANCISCO, CALIFORNIA

DATE: JULY 19, 2006
9 A.M.

REPORTER: BETH C. DRAIN, CSR
CSR. NO. 7152

BRS FILE NO.: 76152

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

I N D E X

ITEM	DESCRIPTION	PAGE NO.
CALL TO ORDER		3
ROLL CALL		11
STAFF REPORT		3
CONSIDERATION OF CIRM MES REGULATIONS SECTION 100095		12
PUBLIC COMMENT		41
ADJOURNMENT		51

1 SAN FRANCISCO, CALIFORNIA; WEDNESDAY, JULY 19, 2006

2 9 A.M.

3

4 CHAIRMAN LO: WHY DON'T WE GO AHEAD AND GET
5 STARTED. I ACTUALLY HAVE A VERY SELFISH REASON. I
6 HAVE ANOTHER MEETING I HAVE TO GO TO AT 10:45 ACROSS
7 THE STREET, SO I NEED TO LEAVE AT ABOUT 10:40. I WAS
8 SORT OF HOPING SELFISHLY THAT WE COULD GET A LOT OF THE
9 DISCUSSION BEFORE THAT SO I WOULDN'T HAVE TO SORT OF
10 MISS IT. I'LL SORT OF TURN THE CHAIRING OVER TO
11 SOMEONE AT THE CIRM HEADQUARTERS, I THINK, WOULD
12 PROBABLY WORK BEST, EITHER GEOFF OR ZACH.

13 FIRST, LET ME JUST WELCOME YOU, AND I
14 APPRECIATE YOUR ALL JOINING THIS. WE'RE SORT OF
15 NEARING THE END OF SORT OF SUBMITTING OUR FINAL PACKAGE
16 OF RECOMMENDATIONS TO THE ICOC ON AUGUST 2D, BUT THERE
17 IS THIS ONE ISSUE THAT I THINK IS SO IMPORTANT THAT WE
18 WANTED TO GATHER YOU AGAIN AND GET YOUR THOUGHTS AND
19 GET PUBLIC THOUGHTS AS WELL BECAUSE IT IS AN IMPORTANT
20 AND DIFFICULT TOPIC.

21 SO LET ME FIRST START BY SAYING I KNOW THERE
22 HAVE BEEN SOME CONCERNS VOICED BY SOME OF THE PUBLIC
23 ABOUT THE WAY THIS MEETING WAS CONVENED AND PUBLIC
24 NOTICE. AND I JUST WANT TO SAY THAT OUR INTENTION
25 CERTAINLY IS NOT TO EXCLUDE THE PUBLIC FROM THESE

1 DISCUSSIONS. AND, IN FACT, THE REASON WE WENT TO THIS
2 ADDITIONAL POSTING WAS AS A RESULT OF SORT OF THINKING
3 THROUGH SOME OF THE ISSUES THAT WERE RAISED IN THE LAST
4 PUBLIC COMMENT PERIOD. HOWEVER, WE ALSO NEED TO BE
5 SOMEWHAT REALISTIC IN THAT THE ICOC MEETING IS AUGUST
6 2D, AND WE WANTED TO GIVE THEM, ALTHOUGH THEY CLEARLY
7 ARE GOING TO MAKE THE FINAL CHOICE ON BOTH APPROVING
8 THE ENTIRE PACKAGE OR MODIFYING IT, WHATEVER, ALSO ON
9 THIS PARTICULAR TOPIC, GIVEN ITS IMPORTANCE AND
10 COMPLEXITY. SO WE THOUGHT IT WOULD BE USEFUL TO
11 PROVIDE THEM WITH SOME GUIDANCE FROM THE SWG.

12 NOW, AS IT TURNS OUT, WE ARE NOT A QUORUM
13 TODAY, SO WE CANNOT ACTUALLY PASS A MOTION, BUT I THINK
14 WE CAN GIVE THEM A SENSE OF THE COMMITTEE, OF THE SWG
15 AS A COMMITTEE, AND ALSO, I THINK, MORE IMPORTANTLY,
16 GIVE THEM A SENSE OF SORT OF THE THOUGHT PROCESS WE
17 ENGAGED IN. MY EXPERIENCE HAS BEEN THAT THE ICOC,
18 ALTHOUGH THEY CLEARLY THINK THROUGH THE ISSUES ON THEIR
19 OWN, REALLY DO APPRECIATE HAVING SORT OF THE TEMPLATE
20 OF OUR THOUGHTS BASED ON THAT.

21 GIVEN THAT THIS WAS -- GIVEN SORT OF WHAT
22 HAPPENS OVER THE SUMMER WITH PEOPLE'S OTHER
23 COMMITMENTS, THIS WAS THE OPTIMAL TIME TO GET THE MOST
24 PEOPLE. AND WE DO APPRECIATE THAT THE PUBLIC COMMENT
25 PERIOD HAS NOT FINISHED, AND WE CERTAINLY WILL REPORT

1 BACK TO THE ICOC AND KEEP IN MIND ALL THE COMMENTS THAT
2 COME RIGHT UP UNTIL THE END OF THE PUBLIC COMMENT
3 PERIOD. BUT GIVEN THAT WE ALREADY HAVE HAD SOME PUBLIC
4 COMMENT AND, AS I SAY, THESE THREE OPTIONS WERE DRAFTED
5 AS SORT OF DIFFERENT APPROACHES TO A QUESTION AND
6 CONCERNS THAT WERE CLEARLY SALIENT AND RAISED
7 IMPORTANCE TO SOME MEMBERS OF THE PUBLIC.

8 WE REALLY WANTED TO USE THIS AS A SENSE OF
9 GETTING THE SWG THINKING ON THREE PROPOSED APPROACHES,
10 AND THESE REALLY ARE OPTIONS. WE LAID THEM ALL OUT
11 JUST SO THAT WE COULD BE KIND OF COMPREHENSIVE AND
12 COMPLETE. AND CERTAINLY IF THE OVERWHELMING SENSE OF
13 THE SWG, THAT ONE OR MORE OF THE OPTIONS IS NOT
14 APPROPRIATE OR ACCEPTABLE, I THINK THAT WOULD BE
15 IMPORTANT TO CONVEY TO THE ICOC AS A SENSE OF THE
16 COMMITTEE ALONG WITH THE RATIONALE FOR WHY WE REJECTED
17 SOME OF THEM.

18 SO THAT WAS JUST TO SORT OF FRAME THIS AND TO
19 TRY AND, YOU KNOW, ASSURE EVERYONE THAT WE'RE NOT
20 TRYING TO CLOSE OFF DISCUSSION ON A DIFFICULT TOPIC,
21 BUT REALLY TO SORT OF MAKE SURE WE HAVE EVERY
22 OPPORTUNITY TO THINK IT THROUGH.

23 WE DID GO BACK -- THIS WAS THE TOPIC THAT WAS
24 DISCUSSED AT THE DECEMBER 1ST MEETING AND THE ACTUAL
25 TRANSCRIPT -- BUT THE TRANSCRIPT, YOU KNOW, DOESN'T

1 REALLY CAPTURE EVERYTHING AND, YOU KNOW, IT WAS HARD,
2 JUST FROM READING THE TRANSCRIPT, TO KNOW THAT WE
3 REALLY THOUGHT ON THIS PARTICULAR ISSUE AS OPPOSED TO A
4 SLIGHTLY DIFFERENT ISSUE INVOLVING USE OF OOCYTES.

5 MR. KLEIN: IF THE OTHER PEOPLE WHO HAVE
6 CONVERSATIONS GOING ON IN THEIR OFFICE COULD JUST MUTE,
7 THAT WOULD BE GREAT.

8 CHAIRMAN LO: OKAY. THANKS. THAT'S A GOOD
9 THOUGHT. WE DO PICK UP BACKGROUND NOISE. IF YOU ARE
10 ON SPEAKER PHONE, JUST PLEASE MUTE IT OR WHATEVER.
11 GREAT. THANKS.

12 OKAY. ANYTHING ELSE THAT, GEOFF, YOU WANT TO
13 ADD, OR, ZACH, YOU WANT TO ADD IN TERMS OF SETTING THE
14 STAGE FOR THIS MEETING OR BOB KLEIN?

15 MR. LOMAX: REALLY JUST FROM MY END, GEOFF
16 LOMAX HERE, TO REMIND PEOPLE, IN ADDITION I'VE SENT TO
17 YOU ALL DRAFTS OF DOCUMENTS THAT WILL BE POSTED IN
18 ADVANCE OF THE ICOC MEETING, AND THEY'RE INFORMATIONAL,
19 BUT THEY WOULD -- ALSO IF INDIVIDUALS HAVE ANY COMMENTS
20 OR HAVE TIME TO LOOK THROUGH THEM, THEY'RE RATHER
21 EXTENSIVE DOCUMENTS. IT INCLUDES OUR SUMMARY OF ALL
22 THE PUBLIC COMMENTS AND HOW WE'VE ADDRESSED THEM AND A
23 DOCUMENT THAT INDICATES ON A SECTION-BY-SECTION BASIS
24 THE BASIS FOR EACH PART OF THOSE REGULATIONS.

25 AND SO MEMBERS ARE AWARE, THOSE DOCUMENTS

1 NEED TO ALSO BE APPROVED BY THE ICOC. THEY WILL SERVE
2 AS THE BASIS FOR OUR STATEMENT OF REASONS.

3 SO THAT IS TRYING TO -- THOSE DOCUMENTS ARE
4 INTENDED TO ESTABLISH THE FACTUAL BASIS FOR OUR
5 SUBMISSION IN ADDITION TO THE ACTUAL WRITTEN LANGUAGE,
6 WHICH, OF COURSE, IS THE CORE OF THE REGULATIONS. SO,
7 AGAIN, THOSE ITEMS WERE SENT TO YOU. THEY'RE
8 INFORMATIONAL, BUT WE DO INTEND TO POST THEM ACCORDING
9 TO THE APPROPRIATE DEADLINES IN ADVANCE OF THE ICOC
10 MEETING FOR THE ICOC'S APPROVAL. SO ANY COMMENTS YOU
11 HAVE ON THOSE, PLEASE DIRECT THEM TO ME.

12 DR. KIESSLING: GEOFF, THIS IS ANN. WHAT
13 DOCUMENTS ARE WE SUPPOSED TO HAVE IN FRONT OF US FOR
14 THIS MEETING?

15 MR. LOMAX: SPECIFIC DOCUMENT FOR THIS
16 MEETING IS A BRIEFING MEMO, AND IT'S TITLED "MES
17 REGULATIONS, SECTION 100095: ADDITIONAL REQUIREMENTS
18 FOR CIRM-FUNDED RESEARCH INVOLVING OOCYTES." AND IT
19 WAS MAILED, I BELIEVE --

20 DR. KIESSLING: OKAY.

21 MR. LOMAX: -- EARLIER THIS WEEK ON MONDAY.
22 IT WOULD HAVE BEEN AFTERNOON YOUR TIME.

23 DR. KIESSLING: RIGHT.

24 DR. TAYLOR: YEAH. 7/17 DRAFT IS WHAT I
25 HAVE.

1 DR. KIESSLING: AND THE SUMMARY TABLE.

2 MR. LOMAX: SORRY. JUST ONE OTHER QUICK
3 REQUEST, JUST, AGAIN, TO SUMMARIZE THE PROCESS. THE
4 ICOC WILL MEET ON AUGUST 2D. THAT MEETING WILL BE THE
5 MEETING IN WHICH WE WOULD ANTICIPATE THEY WOULD APPROVE
6 FINAL REGULATIONS THAT WE WOULD THEN SUBMIT TO THE
7 OFFICE OF ADMINISTRATIVE LAW, WHICH WILL COMPLETE THE
8 PROCESS THAT WE'RE IN AT THE MOMENT. SO WE'VE GONE
9 THROUGH THE PROCESS OF POSTING REGULATIONS. WE'VE GONE
10 THROUGH FOUR ADDITIONAL POSTINGS IN RESPONSE TO PUBLIC
11 COMMENT TO RECEIVE COMMENTS ON ALL THE SECTIONS. THAT
12 WOULD THEN BRING -- THE AUGUST 2D APPROVAL BY THE ICOC
13 WOULD BRING CLOSURE TO THE COMMENT PHASE OF THE
14 REGULATIONS, AND THEN WE WOULD BE SUBMITTING THE FINAL
15 DOCUMENT, AND THE INTENT OF THAT SUBMISSION IS TO MOVE
16 THROUGH THE PROCESS AND HAVE THE ACTUAL REGULATIONS
17 PUBLISHED AS CALIFORNIA LAW.

18 SO WE'RE IN THE TWELFTH HOUR OF STAGE 1,
19 WHICH IS TO INCORPORATE ALL PUBLIC COMMENT AND MAKE
20 NECESSARY CHANGES WITH THE INTENT OF MOVING TO FINAL
21 SUBMISSION.

22 CHAIRMAN LO: ZACH, DO YOU WANT TO ADD
23 ANYTHING IN TERMS OF SETTING THE BACKGROUND FOR THIS?

24 DR. HALL: NO. THAT WAS THE ONLY THING. I
25 HAD JUST ASKED GEOFF TO MAKE THAT SO EVERYBODY KNEW

1 WHERE WE WERE IN THE PROCESS.

2 CHAIRMAN LO: GREAT. BOB KLEIN, ANYTHING YOU
3 WANTED TO SAY AT THIS POINT IN TERMS OF THE BACKGROUND
4 GUIDANCE?

5 MR. KLEIN: WELL, GEOFF, DID WE GET A COMMENT
6 SPECIFICALLY FROM HANK GREELEY ON A PART OF THESE
7 MATERIALS AS TO THE ISSUE OF INTENT?

8 MR. LOMAX: I HAD A DISCUSSION WITH HANK
9 GREELEY, BUT THAT WAS NOT SOMETHING THAT HE ACTUALLY
10 CHOSE TO SUBMIT IN WRITING. I CAN REVISIT THAT
11 DISCUSSION WITH HIM AND ASK IF HE WOULD BE WILLING TO
12 INCLUDE THOSE THOUGHTS IN WRITING, BUT AS OF TODAY WE
13 HAVE NOT RECEIVED COMMENT.

14 MR. KLEIN: OKAY. COULD YOU JUST, A, I THINK
15 IT WOULD BE GOOD TO ASK HIM TO SUBMIT IT, BUT COULD YOU
16 JUST SUMMARIZE IT? THIS IS HANK GREELEY FROM STANFORD
17 LAW SCHOOL, AND I THINK THE DISCUSSION -- THE SUMMARY
18 THAT YOU GAVE ME WAS, I THINK, CONSISTENT WITH MY
19 UNDERSTANDING, BUT IT MIGHT BE HELPFUL TO EVERYONE.

20 CHAIRMAN LO: GEOFF, WHY DON'T WE -- I THINK
21 THAT'S A GREAT IDEA, BOB. AND WHY DON'T WE DO THAT
22 WHEN WE ACTUALLY GET TO THE SPECIFIC TEXT.

23 MR. KLEIN: THAT WOULD BE GREAT.

24 CHAIRMAN LO: IT'S RELEVANT AND WE'LL MAKE
25 SURE THAT GEOFF INCLUDES THAT AN ADDITIONAL SORT OF

1 THOUGHT THAT WE NEED TO KEEP IN MIND. GREAT.

2 ONE OTHER THING, IN TERMS OF THE AGENDA, TED
3 PETERS HAD SUGGESTED THAT WE HAVE A LITTLE BIT OF
4 UPDATE ON SORT OF WHAT'S GOING ON IN WASHINGTON. AND,
5 YOU KNOW, I THINK THAT'S CLEARLY AN IMPORTANT THING.
6 WASHINGTON IS SORT OF BELATEDLY KIND OF TRYING TO
7 FOLLOW CALIFORNIA. BUT I WOULD SUGGEST WE DO THAT
8 MAYBE TOWARDS THE END OF THE CALL, AGAIN BECAUSE,
9 AGAIN, IT'S REALLY SELFISH FOR ME. I'D LIKE TO SORT OF
10 HAVE OUR DISCUSSION OF THIS SECTION.

11 MR. KLEIN: WE DO NEED SOMEONE ELSE TO MUTE
12 AGAIN IN THE BACKGROUND.

13 CHAIRMAN LO: YEAH. YES. THANK YOU.
14 SOMEONE IS --

15 DR. TAYLOR: I'M SORRY. PARDON ME. THIS IS
16 ROB TAYLOR. I'VE DISCOVERED THAT THERE'S NOT A QUIET
17 PLACE IN GRADY MEMORIAL HOSPITAL, MEN'S ROOM INCLUDED.
18 I HAVEN'T TRIED THE WOMEN'S ROOM YET. SO AT SOME POINT
19 THIS MIGHT BE MORE COUNTERPRODUCTIVE THAN PRODUCTIVE.
20 ONE MORE COMPLAINT, AND I'LL GO AHEAD AND SHUT DOWN.

21 MR. KLEIN: WE GREATLY APPRECIATE YOUR
22 PARTICIPATION. UNDER THOSE CIRCUMSTANCES, I THINK WE
23 JUST LIVE WITH IT.

24 DR. HALL: ROB, CAN YOU PUT IT ON MUTE AND
25 THEN TAKE IT OFF WHEN YOU HAVE SOMETHING TO SAY?

1 DR. TAYLOR: I GUESS IF I CAN FIGURE OUT HOW
2 TO DO THAT.

3 CHAIRMAN LO: FIGURE OUT WHERE THE MUTE
4 BUTTON IS.

5 DR. KIESSLING: OR JUST COVER THE MOUTHPIECE
6 WITH SOMETHING.

7 MR. LOMAX: FINALLY, I BELIEVE SOME
8 INDIVIDUALS MAY HAVE JOINED US SINCE WE LAST TOOK ROLL
9 FOR THE RECORD.

10 CHAIRMAN LO: LET'S DO A FORMAL ROLL CALL,
11 GEOFF, SO THAT WE KNOW EXACTLY WHO'S HERE.

12 MR. LOMAX: LET'S GO AHEAD AND DO THAT THEN.
13 THEN WE CAN GET ON WITH THE DELIBERATION.

14 MARCY FEIT.

15 MS. FEIT: HERE.

16 CHAIRMAN LO: HI, MARCY.

17 MS. FEIT: HI.

18 MR. LOMAX: ROBERT KLEIN.

19 MR. KLEIN: HERE.

20 MR. LOMAX: SHERRY LANSING. FRANCISCO
21 PRIETO. JEFF SHEEHY.

22 MR. SHEEHY: HERE.

23 MR. LOMAX: JONATHAN SHESTACK. ALTA CHARO.
24 BERNIE LO.

25 CHAIRMAN LO: HERE.

1 MR. LOMAX: PATRICIA KING.
2 MS. KING: HERE.
3 MR. LOMAX: TED PETERS. KEVIN EGGAN.
4 DR. EGGAN: HERE.
5 MR. LOMAX: ANN KIESSLING.
6 DR. KIESSLING: HERE.
7 MR. LOMAX: JEFFREY KORDOWER, WHO'S HERE ON
8 MUTE. KENNETH OLDEN. JANET ROWLEY. ROBERT TAYLOR.
9 DR. TAYLOR: HERE.
10 MR. LOMAX: JOHN WAGNER.
11 DR. WAGNER: HERE.
12 MR. LOMAX: JAMES WILLERSON. OKAY. THANK
13 YOU.
14 CHAIRMAN LO: OKAY. THANKS. GEOFF, DO YOU
15 WANT TO GIVE US WHAT'S ON THE AGENDA AS A STAFF REPORT,
16 OR HAVE WE ALREADY --
17 MR. LOMAX: WE'VE COVERED THAT, BERNIE.
18 CHAIRMAN LO: WE'VE COVERED THAT. OKAY. I
19 WOULD ACTUALLY LIKE TO SORT OF GO TO, IF IT'S OKAY,
20 WHAT GEOFF SENT OUT. IT'S CALLED SWG BRIEFING MEMO
21 THAT ANN CALLED OUR ATTENTION TO, WHICH I THINK DOES
22 LAY OUT THE ISSUES VERY NICELY. WE'RE TRYING TO FOCUS
23 ON SECTION 100095, ADDITIONAL REQUIREMENTS FOR
24 CIRM-FUNDED RESEARCH INVOLVING OOCYTES.
25 AND, FIRST, I THINK IT'S IMPORTANT, AS GEOFF

1 LAID OUT ON PAGE 1, THAT WE HAVE A, B, C, D, E
2 REQUIREMENTS THAT WE'RE NOT GOING TO DISCUSS TODAY, BUT
3 DO APPLY TO THIS SECTION. AND THE TWO ISSUES THAT WE
4 WANTED TO DEAL WITH ARE, ONE, THE QUESTION OF MIXED EGG
5 DONATION, WHICH I THINK GEOFF EXPLAINS THAT WAS NOT
6 CONTEMPLATED NOR ALLOWED BY ANY OF THESE THREE OPTIONS,
7 AND WE'RE NOT INTENDING THAT A DONOR BE ALLOWED TO
8 DONATE SIMULTANEOUSLY IN THE SAME RETRIEVAL CYCLE TO
9 BOTH A WOMAN IN IVF AND FOR RESEARCH. SO THOSE ARE NOT
10 CONTEMPLATED UNDER OUR THREE OPTIONS.

11 THE SECOND QUESTION IS THE DONATION OF IVF
12 OOCYTES TO RESEARCH IF THEY ARE NOT SUFFICIENTLY MATURE
13 TO BE USED FOR FERTILIZATION FOR REPRODUCTIVE PURPOSES
14 OR IF THEY FAIL TO FERTILIZE. I THINK THE BACKGROUND
15 IS THAT THERE'S SOME INTEREST, THERE'S CONSIDERABLE
16 INTEREST, I GUESS I WOULD SAY, SCIENTIFICALLY IN USING
17 THESE. AND WHAT I'VE HEARD ABOUT IT IS, PARTICULARLY
18 IN THE CONTEXT OF THE CIRM TRAINING GRANTS, WHICH HAVE
19 BEEN FUNDED, THANKS TO BOB'S EFFORT, WHERE THE SITES
20 ARE THINKING THAT IF SOMEONE, A TRAINEE, WANTS TO
21 REALLY LEARN HOW TO WORK WITH HUMAN OOCYTES AFTER, OF
22 COURSE, GETTING THE SKILLS WITH OTHER MAMMALIAN
23 NONHUMAN OOCYTES, THAT IT WOULD MAKE SENSE FOR A LOT OF
24 REASONS TO USE THESE IMMATURE OR FAILED-TO-FERTILIZE
25 OOCYTES RATHER THAN SORT OF STARTING WITH A DEVELOPING

1 TECHNIQUE ON MATURE OOCYTES THAT MIGHT BE BETTER USED
2 IN SORT OF EXPERIENCED HANDS. SO IT'S THAT QUESTION OF
3 ALLOWING THOSE FAILED-TO-FERTILIZE IMMATURE OOCYTES.

4 AND THEN, AGAIN, AS A SUBSET OF THAT WHAT
5 COMES UP IS THAT SOME OF THOSE OOCYTES WILL COME FROM
6 OOCYTE RETRIEVAL CYCLES WHERE THE ORIGINAL OOCYTE
7 DONOR, WHO'S NOT THE WOMAN IN IVF, WAS PAID. AND DO WE
8 WANT TO ALLOW THOSE UNDER CERTAIN CONDITIONS OR FORBID
9 THEM COMPLETELY. AND I THINK THAT'S AN ISSUE THAT DOES
10 GO, AND WHEN WE GET TO THAT, WE'LL SORT OF ASK GEOFF TO
11 SUMMARIZE WHAT HANK GREELEY AT STANFORD, WHO CHAIRS THE
12 STATE HUMAN STEM CELL RESEARCH COMMITTEE, HAS SHARED
13 WITH US ON THAT.

14 BUT DOES THIS SUMMARIZE, GEOFF AND ZACH, SORT
15 OF THE TWO ISSUES WE'RE DEALING WITH HERE?

16 DR. KIESSLING: THIS IS ANN. BEFORE WE GET
17 TO THAT SUMMARY, I ACTUALLY HAVE A COUPLE OF OTHER
18 QUESTIONS ABOUT THIS DRAFT. AND, ROB TAYLOR, ARE YOU
19 STILL ON THE LINE?

20 DR. TAYLOR: I AM.

21 CHAIRMAN LO: GO AHEAD, ANN.

22 DR. KIESSLING: OKAY. AS I -- I THINK THESE
23 ARE SORT OF BEFORE WE GET TO EXACTLY WHAT HAPPENS WITH
24 THE SUPERNUMERARY EGGS. THE PURPOSE OF THESE
25 GUIDELINES AND I THINK THIS DISCUSSION AND I THINK THE

1 CONCERNS ABOUT SUSAN FOGEL AND THOSE FOLKS ARE TO
2 PROTECT THE DONORS, AS I UNDERSTAND IT, RIGHT? AND ONE
3 OF THE THINGS TO PROTECT THE DONORS FROM IS ANY KIND OF
4 CONFLICT OF INTEREST, AND THE BOTTOM LINE IS TO PROTECT
5 THEM FROM AN OVERDOSE OF HORMONE. I THINK THAT'S ONE
6 OF THE SINGLE CONCERNS.

7 AND ALTHOUGH THESE GUIDELINES ARE GETTING
8 VERY DETAILED ABOUT HOW TO CARE FOR HER, THERE'S REALLY
9 NOTHING IN HERE THAT'S GOING TO PROTECT HER OR ANYBODY
10 DONATING EGGS FROM AN OVERDOSE OF HORMONE. AND WHEN
11 YOU START TALKING ABOUT USING EGGS THAT ARE LEFT OVER,
12 IN FACT, YOU SORT OF OPEN UP THAT DOOR A LITTLE BIT.

13 AND I WAS WONDERING IF THE SECTION A, THE
14 CLINIC PERFORMING OOCYTE RETRIEVAL IS A MEMBER OF SART,
15 I WAS WONDERING IF THAT WAS PUT IN THERE TO SORT OF
16 SPEAK TO THE DONOR'S PROTECTION? BECAUSE, IN FACT,
17 SART IS A -- IT'S JUST A STATISTICS ACCUMULATING
18 CENTER. IT DOESN'T PARTICULARLY PROTECT ANYONE FROM AN
19 OVERDOSE OF HORMONE. IT SIMPLY GATHERS STATISTICS, AND
20 IT'S GENERALLY USED TO SIMPLY JUDGE ONE CLINIC AGAINST
21 ANOTHER CLINIC.

22 SO I'M WONDERING IF THERE'S AN OVERARCHING
23 CONCERN ABOUT PROTECTING DONORS FROM EITHER PUTTING
24 THEMSELVES AT RISK WHEN THEY SHOULDN'T OR MAKING SURE
25 THAT THEY'RE NOT SUBJECT TO HYPERSTIMULATION JUST TO

1 COLLECT MORE EGGS.

2 IT MAY BE LANGUAGE IN HERE SHOULD JUST BE
3 MORE DIRECT ABOUT THAT. THE CDC ACTUALLY HAS
4 GUIDELINES THAT WILL LIMIT THE POSSIBILITY FOR
5 HYPERSTIMULATION. I'D LOVE TO HEAR ROB'S COMMENTS ON
6 THAT.

7 CHAIRMAN LO: ROB.

8 DR. TAYLOR: YES. NO. I THINK THAT ANN IS
9 SPOT ON IN TERMS OF WHAT THE ISSUES ARE. SART IS
10 REALLY -- AND THEY'RE ACTUALLY MAYBE NOT THE MAJOR
11 PLAYER ANYMORE. IT'S NOW BEEN SORT OF TURNED OVER TO
12 THE CDC, THE SITE WHERE ALL THE STATISTICS FOR IVF
13 PROGRAMS ARE FUNNELED. BUT SART ALSO HAS BEEN KIND OF
14 A CLEARINGHOUSE FOR THE MORE COMPLIANT PROGRAMS AROUND
15 THE COUNTRY, AND IT'S BEEN THE PLACE WHERE SART
16 CERTIFICATION HAS KIND OF, I THINK, IDENTIFIED PROBABLY
17 THE BEST PRACTICES IN IVF. SO FOR ME THAT WAS SORT OF
18 THE ADVANTAGE OF HAVING THE STIPULATION THAT THEY BE
19 SART MEMBERS. SO MUCH THAT THAT'S WHERE THE BIOSTAFF
20 SAT, BUT THAT THEY HAD A LITTLE BIT MORE OF A RIGOROUS
21 SORT OF CERTIFICATION PROCESS FOR THE IVF PROGRAMS.

22 ON THE OTHER SIDE OF THAT, THOUGH, I THINK
23 THAT THE SUBTLE CONCERN ABOUT SUPERNUMERARY EGGS BEING
24 NOW AVAILABLE FOR RESEARCH PURPOSES AND
25 FAILURE-TO-FERTILIZE OOCYTES, WHICH WOULD TEND TO BE

1 PROBABLY LESS MATURE EGGS THAT YOU MIGHT HAPPEN TO PICK
2 UP IF YOU'RE BEING MORE AGGRESSIVE ABOUT PICKING UP
3 EGGS, I DO THINK THAT THIS IS KIND OF THE SLIPPERY
4 SLOPE OF THAT ISSUE AND PROBABLY WILL BE A RELATIVE
5 INCENDIARY KIND OF A POINT FOR PEOPLE BELIEVING THAT
6 THESE DONORS NOW MIGHT BE AT INCREASED RISK BECAUSE
7 THERE IS SORT OF A SUBTLE ATTEMPT AT GENERATING MORE
8 EGGS BECAUSE THEY CAN THEN BE USED FOR THE SECONDARY
9 PURPOSE.

10 SO I THINK THAT'S PROBABLY WHERE THE
11 COMPLAINTS ARE GOING TO COME FROM. I'M NOT REALLY
12 ANSWERING THE QUESTION, BUT JUST KIND OF POSING IT IN A
13 WAY. SO I DON'T THINK SART MATTERS SO MUCH OTHER THAN
14 TO KIND OF IDENTIFY MAYBE SOME OF THE BEST PRACTICES IN
15 IVF. BUT I THINK THAT THERE IS GOING TO BE SORT OF A
16 SUBTLE CONCERN THAT WE MIGHT BE COERCIVE AND THAT WE
17 WOULD BE MORE AGGRESSIVE IN EITHER RETRIEVING MORE
18 IMMATURE EGGS OR PUSHING GONADOTROPINS HARDER TO GET
19 MORE EGGS IF SUPERNUMERARY EGGS COULD BE USED FOR --
20 YOU KNOW, FAILURE-TO-FERTILIZE EGGS COULD BE USED FOR
21 SOME OF THESE TRAINING PURPOSES OR FOR THE PURPOSES OF
22 GENERATING STEM CELLS.

23 DR. HALL: DOESN'T STATEMENT ONE UNDER ALL
24 THREE OPTIONS, I THINK THAT -- I THOUGHT THAT WAS THE
25 INTENT OF THAT. IT SEEMED TO ME VERY CLEAR THAT THE

1 TREATMENT PROTOCOL IS ESTABLISHED PRIOR TO REQUESTING
2 OR OBTAINING CONSENT FOR A DONATION FOR RESEARCH
3 PURPOSES. AND THE PROSPECT OF DONATION FOR RESEARCH
4 DOES NOT ALTER THE TIMING, METHOD, OR PROCEDURE
5 SELECTED FOR CLINICAL CARE. ISN'T THAT MEANT TO
6 PROTECT THAT VERY POINT, IMPORTANT POINT THAT THE TWO
7 OF YOU RAISE?

8 DR. KIESSLING: ZACH, ONE OF THE BIG CONCERNS
9 HERE, I THINK, THAT SOME PEOPLE ARE TRYING TO PROTECT
10 THE DONORS BY SIMPLY NOT COMPENSATING THEM. I THINK
11 ONE OF THE REALLY LARGE CONCERNS IS THAT IF YOU'RE
12 ATTEMPTING A PREGNANCY, IT'S VERY -- IT'S RECOGNIZED
13 CLINICAL JUDGMENT THAT YOU MIGHT PUT THIS WOMAN AT RISK
14 FOR HYPERSTIMULATION BECAUSE SHE'S ATTEMPTING A
15 PREGNANCY. AND SO IF SOMEBODY IS COMING THROUGH, AND
16 WEIGH IN ON THIS, ROB, IF I'M OFF BASE, BUT IF SOMEBODY
17 IS COMING THROUGH AND SHE'S RESPONDED A LITTLE MORE
18 THAN YOU'D LIKE TO THE HORMONE TREATMENT, YOU'RE
19 WILLING TO PUT HER AT SOME RISK BECAUSE SHE'S BEEN
20 WAITING A LONG TIME TO HAVE CHILDREN, ON AND ON AND ON.
21 THIS IS A CLINICAL JUDGMENT.

22 IF SOMEONE IS COMING THROUGH FOR A RESEARCH
23 PURPOSE, THAT SHOULD NOT BE A CONSIDERATION. THERE
24 SHOULD BE A ZERO TOLERANCE FOR HYPERSTIMULATION.

25 DR. HALL: OKAY. BUT I DON'T THINK THAT'S

1 WHAT'S AT ISSUE HERE, ANN. I THINK THE QUESTION WE'RE
2 DISCUSSING IS --

3 DR. KIESSLING: I THINK IT'S THE HEART OF THE
4 MATTER, ZACH, BECAUSE I DON'T THINK ANYBODY WOULD BE
5 CONCERNED ABOUT THE DONORS PUTTING THEMSELVES AT RISK
6 IF IT WEREN'T FOR THE RISK OF THE HORMONE TREATMENT.

7 DR. HALL: I UNDERSTAND THAT AND I HOPE -- I
8 MEAN THAT'S AN ISSUE FOR PEOPLE WHO COME TO GIVE JUST
9 FOR RESEARCH; ISN'T THAT CORRECT?

10 DR. KIESSLING: NO. IT'S AN ISSUE FOR
11 EVERYONE WHO'S GOING THROUGH HORMONE TREATMENT.

12 CHAIRMAN LO: LET ME TRY AND STEP IN A SECOND
13 BECAUSE I THINK IT IS AN IMPORTANT POINT, AND WE
14 STRUGGLED WITH THIS WITH THE STAFF. LET ME JUST FIRST
15 EXPLAIN WHY A IS IN THERE. THAT SART IS IN THE PROCESS
16 OF DRAFTING STANDARDS OF CLINICAL PRACTICE, AND THEY'RE
17 NOT OUT YET. AND WE TRIED TO SORT OF GET AHOLD OF
18 THEM, AND ACTUALLY THEY SAID THEY WOULD SEND IT.

19 DR. KIESSLING: BERNIE, I HAVE NO OBJECTION
20 TO A. I THINK THAT'S A FINE REGULATION. I JUST DIDN'T
21 WANT ANYBODY TO THINK THAT SART HAS RIGHT NOW
22 GUIDELINES FOR PREVENTING HYPERSTIMULATION BECAUSE THEY
23 DO NOT.

24 CHAIRMAN LO: RIGHT. RIGHT.

25 DR. KIESSLING: BUT THE CDC DOES. AND IF THE

1 GOAL OF A IS TO PROTECT DONORS FROM ANY RISK
2 WHATSOEVER, EVEN A PERCEIVED RISK OF HYPERSTIMULATION,
3 THEN THE CDC GUIDELINES WOULD -- I'M NOT SAYING TO GET
4 RID OF THE A. I WAS JUST HOPING THAT NO ONE THOUGHT
5 THAT THAT COVERED THAT AS A RISK.

6 CHAIRMAN LO: I THINK THAT'S A GOOD POINT.
7 IF YOU COULD SEND US A REFERENCE OR SEND US THE CDC
8 GUIDELINES, I THINK, ROB, WE'LL COUNT ON YOU AGAIN. I
9 THINK AS ZACH POINTS OUT, AND MAYBE WE NEED TO SORT OF
10 DO A BETTER JOB, IT'S A VERY IMPORTANT POINT IN TERMS
11 OF PROTECTING WOMEN WHO ARE DONATING. THIS COMES TO
12 TOGETHER AT DIFFERENT PLACES, AND I THINK THE POINT YOU
13 RAISE, ANN, IN TERMS OF RISKS THAT ARE ACCEPTABLE IN A
14 CLINICAL IVF CONTEXT MAY NOT BE ACCEPTABLE OR WILL NOT
15 BE ACCEPTABLE IN THE PURELY RESEARCH CONTEXT, I THINK,
16 IS AN IMPORTANT ONE. AND WE DISCUSSED THAT, I
17 REMEMBER, AT ONE OF OUR MEETINGS. SO I THINK LET'S --
18 I DON'T THINK THERE'S ANY DISCUSSION -- THERE'S ANY
19 DISAGREEMENT ABOUT NOT WANTING TO HAVE SOMETHING
20 SPECIFIC IN THE REGULATIONS. WE NEED TO BE SPECIFIC SO
21 PEOPLE KNOW WHAT THEY HAVE TO DEAL WITH OR WHAT THEY
22 HAVE TO DO. SO WE COULD NOT HAVE JUST SAID, WHICH THE
23 FEDERAL REGULATIONS DO, YOU HAVE TO MINIMIZE RISKS
24 WHICH, THEY HAVE TO ANYWAY, LIKE OUR INCORPORATION OF
25 THE COMMON RULE. WE ARE HELD TO A MORE SPECIFIC

1 STANDARD; BUT IF THERE IS A SET OF SORT OF PROFESSIONAL
2 STANDARDS FROM CDC OR FROM ANY OTHER ORGANIZATION --

3 DR. KIESSLING: I DON'T KNOW IF THEY'RE
4 PROFESSIONAL STANDARDS.

5 DR. HALL: CAN I JUST INTERVENE HERE? IT'S
6 RELEVANT TO KNOW THAT OUR PLANS FOR OUR CONFERENCE ON
7 ASSESSMENT OF MEDICAL RISK FOR EGG DONORS HAVE GONE
8 FORWARD, AND THAT CONFERENCE ACTUALLY WILL BE HELD
9 EITHER ON SEPTEMBER 21ST OR 28TH IN SAN FRANCISCO. IT
10 IS SPONSORED BY THE IOM. IT IS A COMMITTEE OF EIGHT
11 PEOPLE CHAIRED BY LINDA GUIDICE, WHICH WILL ORGANIZE,
12 CHOOSE THE SPEAKERS, AND RUN THE CONFERENCE, AND THEY
13 WILL MAKE A REPORT TO US AFTERWARDS. AND ONE OF THE
14 ISSUES AT THE CONFERENCE IS ARE THERE WAYS IN WHICH
15 RISK CAN BE MITIGATED FOR WOMEN WHO DONATE EGGS.

16 AND SO MY HOPE IS THAT WE WILL COME OUT OF
17 THAT CONFERENCE WITH RECOMMENDATIONS EITHER BASED ON
18 CDC OR OTHERS THAT WILL BE VERY IMPORTANT AND THAT WILL
19 BE APPLICABLE, I THINK, SPECIFICALLY FOR PEOPLE WHO ARE
20 GIVING EGGS FOR RESEARCH PURPOSES.

21 CHAIRMAN LO: OKAY.

22 DR. EGGAN: HEY, ZACH. THIS IS KEVIN. AS
23 SOON AS THE TIMING OF THAT MEETING IS FINALIZED, CAN
24 YOU LET US KNOW?

25 DR. HALL: WE CERTAINLY WILL. WE ABSOLUTELY

1 WILL. IT WILL BE WEBCAST LIVE, SO IT WILL BE
2 ACCESSIBLE TO EVERYBODY.

3 CHAIRMAN LO: THAT'S GREAT. I THINK THIS
4 WILL BE AN EXTREMELY IMPORTANT AND USEFUL MEETING.

5 MR. LOMAX: DID SOMEONE JUST JOIN THE CALL?
6 DID SOMEONE JUST JOIN THE CALL?

7 MS. CHARO: YES. IT'S ALTA. SORRY ABOUT
8 BEING LATE.

9 MR. LOMAX: WE NOW HAVE A QUORUM, BERNIE.
10 JUST FYI.

11 CHAIRMAN LO: OKAY. GOOD. SO, ANN, LET'S
12 SAY WE CLEARLY AGREE WITH THE CONCERN YOU RAISE, WHICH
13 HAS BEEN RAISED VERY ELOQUENTLY AS WELL BY A NUMBER OF
14 OUR PUBLIC COMMENTATORS, AND I THINK WE WILL -- YEAH,
15 WE CERTAINLY, IF WE CAN SORT OF PUT IN REGULATORY
16 LANGUAGE EITHER IN THIS DRAFT, IF IT'S NOT TOO LATE,
17 OR, OF COURSE, WE CAN MODIFY THIS AFTER THE SEPTEMBER
18 CONFERENCE IF THERE'S SOMETHING THERE THAT, FOR
19 INSTANCE, CDC STANDARDS SHOULD APPLY.

20 DR. KIESSLING: I'LL SEND SOME SPECIFIC
21 LANGUAGE TO GEOFF.

22 CHAIRMAN LO: OKAY. THAT'S GREAT.

23 DR. EGGAN: ALSO, THIS IS KEVIN EGGAN. I
24 WOULD JUST ECHO ANN'S COMMENTS. WHEN WE LOOK TO SEE
25 WHETHER OR NOT WE'RE INTERESTED IN COLLABORATING WITH A

1 PARTICULAR IVF CLINIC OR LOOKING AT THE ACTIVITY OF AN
2 IVF CLINIC, WE ALMOST ALWAYS GO TO THE CDC INFORMATION.

3 CHAIRMAN LO: GOOD. SO THAT'S USEFUL. SO
4 LET'S KEEP THAT UNDER ADVISEMENT. AND, AGAIN, JUST TO
5 MAKE SURE WE'RE ALL ON THE SAME PAGE, WHAT GEOFF LOMAX
6 FORMULATED AS QUESTION 1 ON PAGE 2 OF THIS BRIEFING
7 MEMO, MIXED EGG DONATION IS NEITHER CONTEMPLATED NOR
8 ALLOWED BY THESE REGULATIONS UNDER ANY OF THESE OPTIONS
9 A, B, C WE'RE CONSIDERING TODAY. JUST WANT TO MAKE
10 SURE THAT WE AGREE WITH THAT AND THAT'S SORT OF, AGAIN,
11 THE STARTING POINT, I THINK, FOR WHAT BECOMES THE MEAT
12 OF OUR DISCUSSION.

13 DR. HALL: THIS IS BASED JUST UPON -- BERNIE,
14 THIS IS BASED ON A VERY IMPORTANT PRINCIPLE I THINK
15 FIRST ENUNCIATED BY TED PETERS, THAT WE SHOULD NOT
16 COMPROMISE REPRODUCTIVE SUCCESS.

17 CHAIRMAN LO: RIGHT. RIGHT. AND, ZACH, WE
18 CRAFTED THAT EXACTLY SAYING THAT THE PROCUREMENT AND
19 DISPOSITION OF OOCYTES INITIALLY PROVIDED FOR
20 REPRODUCTIVE USES SHALL NOT KNOWINGLY COMPROMISE THE
21 OPTIMAL REPRODUCTIVE SUCCESS OF THE WOMAN IN FERTILITY
22 TREATMENT. AGAIN, IT'S A WAY OF TRYING TO PROTECT
23 WOMEN IN IVF TREATMENT WHO MAY NOT BE THE SAME AS THE
24 OOCYTE DONOR.

25 OKAY. WITH THAT BACKGROUND, THEN WE GO TO

1 QUESTION 2, WHICH IS ON THE BOTTOM OF GEOFF'S PAGE 3 OF
2 HIS DRAFT, WHICH IS LOOKING TO OUR THREE OPTIONS THAT
3 WE LAY OUT ON SUBSEQUENT PAGES. IT'S REALLY THIS
4 QUESTION OF DONATION OF OOCYTES THAT WERE ORIGINALLY
5 INTENDED FOR USE IN IVF, BUT TURNED OUT NOT TO BE
6 USABLE FOR THAT PURPOSE. AND, AGAIN, THE SPECIFIC
7 CLINICAL SCENARIOS ARE IMMATURE, SO THEY DON'T EVEN
8 ATTEMPT TO FERTILIZE THEM, BUT THEY MAY BE USEFUL FOR
9 RESEARCH, OR THEY DID ATTEMPT TO FERTILIZE AND THEY
10 FAILED TO FERTILIZE, AND THEY STILL MIGHT BE USED FOR
11 RESEARCH PURPOSES.

12 MY UNDERSTANDING IS THAT THESE OOCYTES WHICH
13 ARE TOO MATURE TO BE USED FOR REPRODUCTION OR FAIL TO
14 FERTILIZE ARE OTHERWISE DISCARDED OR GIVEN TO SOME
15 OTHER PERHAPS RESEARCH PURPOSE IF NOT TO A CIRM-FUNDED
16 RESEARCHER. SO THERE IS NO COMPROMISE OF REPRODUCTIVE
17 SUCCESS, ASSUMING THAT THE DETERMINATION OF WHAT'S
18 FAILED TO FERTILIZE AND WHAT'S TOO MATURE WAS MADE IN
19 AN UNBIASED WAY. ONE OF THE OPTIONS TALKS TO THAT.

20 SO THAT'S THE BACKGROUND OF THESE THREE
21 OPTIONS, OPTIONS 1, 2, AND 3. AND GEOFF GIVES SORT OF
22 A SCHEMATIC, A VISUAL SCHEMATIC AT THE BOTTOM OF PAGE
23 4, WHICH I THINK IS A GOOD ONE. AND I JUST WANT TO
24 POINT OUT THAT LAST ARROW FROM THE, I SUPPOSE IT'S A
25 WOMAN IN WHITE, TO THE RESEARCH MICROSCOPE, THAT

1 TRANSITION ONLY OCCURS IF THE OOCYTES, YOU KNOW, ARE
2 NOT USABLE FOR HER REPRODUCTIVE PURPOSES.

3 SO WITH THAT IN MIND, LET'S TURN TO THE THREE
4 OPTIONS. AND HERE THE ISSUE NOW CENTERS ON PAYMENT,
5 AND THE SUBSET OF OOCYTE DONORS WHO ARE PAID TO DONATE
6 ORIGINALLY FOR IVF, BUT TURNS OUT THEIR OOCYTES OR SOME
7 OF THEIR OOCYTES, A FEW OF THEM, CAN'T BE USED FOR
8 THAT, ARE THOSE OOCYTES USABLE UNDER THE RESTRICTIONS
9 OF PROP 71?

10 AND I PULLED UP PROP 71 AGAIN JUST SO I MADE
11 SURE I HAD THE LANGUAGE, AND THE PROHIBITION IS THAT
12 THE ICOC SHALL ESTABLISH STANDARDS. AND ONE OF THE
13 STANDARDS IS STANDARDS PROHIBITING COMPENSATION TO
14 RESEARCH DONORS OR PARTICIPANTS WHILE PERMITTING
15 REIMBURSEMENT OF EXPENSES.

16 NOW, ON THE ONE HAND, IT'S A LEGAL
17 INTERPRETATION OF ISSUES, SORT OF WHAT THAT LANGUAGE
18 MEANS. AND AN UNDERSTANDING BASED ON WHAT JAMES
19 HARRISON SAID A NUMBER OF MEETINGS AGO WAS THAT IT'S
20 REALLY AN ISSUE ULTIMATELY FOR THE COURTS TO DECIDE.
21 IT REALLY ISN'T AS MUCH, YOU KNOW -- I HAD MISTAKENLY
22 THOUGHT IT'S WHAT BOB KLEIN AND HIS TEAM THOUGHT IT
23 MEANT, BUT WE WERE TOLD THAT LEGALLY IT'S WHAT -- HOW
24 THE COURTS INTERPRET THE LANGUAGE. AND THERE ARE
25 PEOPLE, AND I THINK SOME OF THE MEMBERS OF THE

1 COMMUNITY HAVE ALREADY STRONGLY EXPRESSED TO ME THE
2 OPINION THAT IN THEIR VIEW THAT TEXT OF PROP 71 SORT OF
3 MAKES IT UNACCEPTABLE FOR US TO USE THESE
4 FAILED-TO-FERTILIZE IMMATURE OOCYTES IF THE ORIGINAL
5 OOCYTE DONOR WAS PAID. AND THAT IS ONE OF THE OPTIONS
6 WE LAID OUT.

7 I THINK, ALTHOUGH THIS MAY SEEM TO BE A MINOR
8 POINT, I THINK IT'S WORTH CLARIFYING BECAUSE IT'S ONE
9 OF THE SPECIFIC ISSUES THAT I KNOW THE TRAINING
10 PROGRAMS FUNDED BY CIRM ARE STRUGGLING WITH AS THEY
11 THINK ABOUT HOW TO PROVIDE THE TRAINING THAT WE WANT
12 THESE YOUNG SCIENTISTS TO HAVE. SO LET ME STOP THERE
13 AND, AGAIN, GEOFF OR ZACH, YOU WANT TO SORT OF ADD IN
14 ANYTHING, AND THEN WE'LL THROW IT OPEN FOR DISCUSSION.

15 MR. LOMAX: NOTHING AT THIS END.

16 DR. HALL: EXCELLENT SUMMARY.

17 CHAIRMAN LO: OKAY. SO WHY DON'T -- LET'S
18 JUST HEAR -- I REALLY WANT TO HEAR WHAT YOU FOLKS FROM
19 THE COMMITTEE AND THEN ALSO FROM THE PUBLIC THINK ABOUT
20 THIS ISSUE. JEFF SHEEHY, DO YOU WANT TO START US OFF
21 BECAUSE I KNOW YOU HAVE THOUGHT ABOUT THIS A LOT AND
22 HAVE A VIEW YOU'VE WORKED OUT.

23 MR. SHEEHY: SURE. PERSONALLY I WOULD OPT
24 FOR OPTION 3, WHICH IS A STRONG PROHIBITION. I JUST
25 THINK IT IS A SLIPPERY SLOPE. I THINK PROP 71 IS

1 PRETTY EXPLICIT ON NONCOMPENSATION. I DON'T THINK OUR
2 REGULATORY FRAMEWORK IS ROBUST ENOUGH TO PREVENT ABUSE.
3 WE'RE REALLY RELYING TO A LARGE DEGREE ON
4 SELF-REGULATION BY THE INSTITUTIONS. AND THE
5 INSTITUTIONS THEMSELVES WILL NOT HAVE A REGULATORY ROLE
6 WITH THE IVF CLINICS, WHICH TO MY MIND NO ONE HAS A --
7 I MEAN MY UNDERSTANDING IS THAT IT REALLY ISN'T A
8 REGULATORY FRAMEWORK ANYWAY FOR IVF CLINICS.

9 SO WE'RE KIND OF -- I JUST -- THIS IS EXACTLY
10 THE KIND OF ISSUE THAT MADE ME VERY LEERY ABOUT
11 INVOLVING IVF CLINICS IN THE EGG DONATION AT ALL.

12 CHAIRMAN LO: GREAT. OTHERS? I'M SORRY I
13 CAN'T SEE YOUR HANDS. JUST JUMP IN.

14 DR. KIESSLING: BERNIE, I ACTUALLY THINK IT'S
15 A PRETTY SMALL NUMBER OF EGGS AT RISK, RIGHT? I MEAN I
16 THINK FROM A PRACTICAL STANDPOINT, YOU KNOW, I SORT OF
17 DEGREE WITH JEFF. I THINK IT'S CLEAR IT'S PROBABLY NOT
18 ALLOWED, BUT I THINK FROM A PRACTICAL STANDPOINT, I
19 DON'T THINK IT AMOUNTS TO A VERY GREAT LOSS OF
20 RESOURCE.

21 DR. TAYLOR: I AGREE WITH ANN. THIS IS ROB
22 TAYLOR. THE NUMBER OF KIND OF IMMATURE EGGS THAT WE'RE
23 TALKING ABOUT FROM DONORS, WHICH IS ALREADY A SMALL
24 PROPORTION OF THE TOTAL NUMBER OF IVF-GENERATED
25 PREGNANCIES, IS SORT OF TOO SMALL A NUMBER TO REALLY

1 PUT OURSELVES ON THE LINE GIVEN WHAT SEEM TO BE VERY
2 STRAIGHTFORWARD AND STRINGENT STIPULATIONS ABOUT
3 COMPENSATION IN PROP 71.

4 CHAIRMAN LO: SO YOU WOULD AGREE WITH OPTION
5 3, THE ONE JEFF ORIGINALLY POINTED TO?

6 DR. TAYLOR: I THINK FROM MAYBE JUST A
7 PRAGMATIC STANDPOINT, I JUST DON'T KNOW THAT IT'S WORTH
8 FIGHTING THAT FIGHT.

9 CHAIRMAN LO: OKAY. OKAY. OTHER THOUGHTS?
10 OTHER OPINIONS?

11 DR. EGGAN: THIS IS KEVIN, AND I ECHO THAT
12 SAME POINT OF VIEW. I THINK IT'S GOING TO BE A VERY
13 SMALL AMOUNT OF MATERIAL IN ANY CASE, AND I THINK IT'S
14 TOO AMBIGUOUS.

15 CHAIRMAN LO: OKAY. ALTA, PAT, YOU'RE OUR
16 LEGAL SCHOLARS. YOU WANT TO SORT OF CHIME IN? I KNOW
17 THIS HAS COME UP IN YOUR WORK AS WELL.

18 MS. CHARO: WELL, AS A LEGAL MATTER, IT
19 STRIKES ME THAT YOU CAN'T ACTUALLY DEVELOP THIS IN A
20 WAY THAT MAKES IT CLEAR THAT ANY DONATION TAKES PLACE
21 INDEPENDENT OF COMPENSATION. WITH THAT SAID, AS A
22 MATTER OF SIMPLICITY, A BRIGHT LINE RULE HAS THE
23 ADVANTAGE OF BEING EASY TO UNDERSTAND AND EASY TO
24 IMPLEMENT, WHICH MAKES ME AGREE WITH THE COMMENTS THAT
25 HAVE BEEN MADE.

1 CHAIRMAN LO: PAT KING, ARE YOU STILL THERE?

2 MS. KING: YES, I'M STILL HERE.

3 CHAIRMAN LO: WHAT ARE YOUR THOUGHTS ON THIS
4 ONE?

5 MS. KING: I ACTUALLY AGREE WITH JEFF, AND
6 IT'S NOT AS A LEGAL ISSUE OR ETHICAL ISSUE. AS A
7 PRACTICAL MATTER, I JUST THINK, GIVEN ALL THE AREAS
8 THAT WE CAN'T DIRECTLY CONTROL, GIVEN SOME OF THE
9 CONCERNS ABOUT THIS ISSUE, ESPECIALLY HEARING ABOUT THE
10 SMALL NUMBER OF EGGS, I JUST THINK IT'S NOT WORTH IT.
11 SO I WOULD GO WITH OPTION 3.

12 CHAIRMAN LO: OKAY. OKAY. NOW, GEOFF LOMAX,
13 AS I RECALL, THIS WAS AN ISSUE THAT YOU AND HANK
14 GREELEY DISCUSSED. YOU WANT TO -- WOULD THIS BE A TIME
15 TO SORT OF GIVE HANK'S VIEWS ON THIS?

16 MR. LOMAX: WELL, PERHAPS I CAN -- I THINK
17 ALTA, I THINK, PROBABLY ALSO WOULD ECHO THAT, BUT I
18 HATE TO SORT OF INVOKE HANK IN A CONTEXT WHERE I DON'T
19 KNOW IF HE INTENDED THE DISCUSSION TO GO.

20 CHAIRMAN LO: OKAY.

21 MR. LOMAX: BUT I THINK IN TERMS OF, AND I
22 WILL SAY CONSISTENTLY A NUMBER OF PEOPLE WITH LEGAL
23 TRAINING WHO LOOKED AT SORT OF THE LETTER OF THE
24 LANGUAGE AND THE CONTEXT, DID ARGUE -- SAY THERE'S
25 CERTAINLY A CASE TO BE MADE WHERE BY HAVING THE PAID

1 DONOR THEN BASICALLY GIVE DISPOSITIONAL AUTHORITY TO
2 ANOTHER WOMAN, THAT THERE WAS A LEGAL INTERPRETATION
3 THAT THIS IS REASONABLE, BUT, AGAIN, IT'S LOOKING AT IT
4 THROUGH THE LEGAL LENS. AND I THINK --

5 CHAIRMAN LO: RIGHT.

6 MR. LOMAX: PAT, I THINK, SUMMED UP -- EXCUSE
7 ME -- ALTA SUMMED UP THAT VIEW NICELY. THERE'S A CASE
8 THAT COULD BE MADE, AND IT'S SORT OF A TRADE-OFF
9 BETWEEN MAKING A SOMEWHAT NUANCED LEGAL ARGUMENT VERSUS
10 A BRIGHT LINE TEST. I THINK THAT'S SORT OF THE BOTTOM
11 LINE FOR THE WORKING GROUP.

12 CHAIRMAN LO: WHAT I'VE HEARD IS A NUMBER OF
13 PEOPLE, JEFF, ANN, ROB, KEVIN, ALTA, AND THEN PAT ALL
14 SAYING THAT THEY WOULD COME DOWN IN FAVOR OF OPTION 3,
15 WHICH IS THE PROHIBITION ON OOCYTES WHERE THE DONOR
16 ORIGINALLY WAS PAID.

17 IS THERE ANYONE WHO WANTS TO RAISE A
18 DIFFERENT THOUGHT OR DIFFERENT PERSPECTIVE ON THAT?

19 DR. EGGAN: I HAVE ONE POINT TO MAKE. THIS
20 ISSUE ABOUT WHETHER OR NOT THE WOMAN WHO PAID THE
21 REPRODUCTIVE DONOR FOR THE OOCYTES AS TO WHETHER OR NOT
22 SHE HAS THE LEGAL RIGHT TO THEN DONATE THEM AFTERWARDS.
23 IT MAY BE IN CALIFORNIA THAT THIS IS THE CASE, BUT
24 CERTAINLY I KNOW THAT IN MASSACHUSETTS, AND I'M NOT
25 SURE IF THE NAS GUIDELINES SPEAK TO THIS ISSUE, BUT

1 SOME STATE LEGISLATURES, INCLUDING IN MASSACHUSETTS,
2 HAVE DECIDED THAT BECAUSE OF THE SENSITIVITY AROUND
3 STEM CELL RESEARCH, THAT THE REPRODUCTIVE DONOR HERSELF
4 WOULD HAVE TO CONSENT AS WELL AS THE WOMAN WHO'S
5 RECEIVING THE OOCYTES. AND THE SAME WOULD BE TRUE FOR
6 ANY RESULTING DISCARDED IVF EMBRYOS THAT MIGHT RESULT
7 FROM THAT REPRODUCTIVE EFFORT.

8 CHAIRMAN LO: YES. AND THAT'S ACTUALLY IN
9 ANOTHER PART OF OUR PROPOSED GUIDELINES. WE TAKE
10 EXACTLY THE POSITION YOU OUTLINED, THAT YOU NEED TO GET
11 CONSENT BOTH FROM THE WOMAN IN SORT OF IVF TREATMENT,
12 BUT FROM THE ORIGINAL GAMETE PROVIDERS IF THEY ARE
13 DIFFERENT THAN THE COUPLE IN IVF.

14 DR. EGGAN: SO I GUESS WHAT I'M SAYING IS
15 DOES THAT MEAN THAT IN THIS PARTICULAR INTEREST -- YOU
16 KNOW, INSTANCE ARE WE ALREADY SAYING THAT BECAUSE OF
17 THE SENSITIVITY SURROUNDING STEM CELL RESEARCH, THAT
18 ALTHOUGH IT'S TRUE THAT THE WOMAN MAY HAVE PURCHASED
19 THAT MATERIAL, SHE MAY HAVE MORE LIMITED RIGHTS TO THAT
20 MATERIAL THAN MIGHT BE THE CASE IN OTHER SITUATIONS? I
21 GUESS -- I GUESS I'M TRYING TO HIGHLIGHT THAT POINT OR
22 COUNTERPOINT WHAT JEFF SAID.

23 CHAIRMAN LO: I THINK THAT'S RIGHT.
24 GIVEN -- IF YOU PUT THIS PARTICULAR BULLET IN THE
25 CONTEXT OF EVERYTHING ELSE, IT'S CLEAR, IT SHOULD BE

1 CLEAR THAT WE WOULD REQUIRE CONSENT FROM THE OOCYTE
2 DONOR FOR USE OF THE OOCYTE OR EMBRYOS IN CIRM-FUNDED
3 RESEARCH.

4 MR. LOMAX: IN FACT, IN DISCUSSION WITH
5 COUNSEL HERE, THAT WAS -- THAT POINT WAS RAISED. GIVEN
6 THAT WE'RE ALREADY REQUIRING CONSENT FROM THE ORIGINAL
7 DONOR OF THE MATERIALS, THAT WOULD -- THAT SORT OF
8 COMPLICATES THE ANALYSIS IN TERMS OF ARE THE MATERIALS
9 BEING GIVEN FOR VALUABLE CONSIDERATION. SO THAT POINT
10 WAS TAKEN UNDER CONSIDERATION.

11 DR. TAYLOR: I WOULD THINK SO. THE
12 DISPOSITIONAL AUTHORITY BECOMES REALLY QUITE SPECIOUS,
13 IN MY VIEW, IF THERE'S ALREADY CONSENT GIVEN BY THE
14 BIOLOGICAL DONOR.

15 CHAIRMAN LO: I'M SORRY. IS THAT SCOTT?

16 DR. HALL: I THINK THAT WAS ROB TAYLOR.

17 CHAIRMAN LO: ROB TAYLOR. YOU'RE TALKING
18 LIKE A LAWYER, ROB.

19 DR. TAYLOR: HEY.

20 CHAIRMAN LO: I'M SORRY. I DIDN'T WRITE DOWN
21 EVERYBODY ON THE CALL. I JUST WANT TO MAKE SURE PEOPLE
22 WHO HAVEN'T SPOKEN, JOHN WAGNER, MARCY. I DON'T KNOW
23 IF THERE'S ANYONE ELSE.

24 DR. HALL: BOB KLEIN.

25 CHAIRMAN LO: BOB, I'M SORRY, YES,

1 ABSOLUTELY. BOB. ANY OF YOU WANT TO SORT OF GIVE US
2 YOUR VIEWS AS WELL HERE?

3 MS. FEIT: THIS IS MARCY FEIT. I THINK I
4 AGREE WITH EVERYBODY ON OPTION 3. IF IT'S A MATTER OF
5 JUST A SMALL AMOUNT OF MATERIAL THAT'S GOING TO BE
6 CONSIDERED, THERE SHOULDN'T BE A REASON TO GO ANY OTHER
7 ROUTE.

8 DR. WAGNER: THIS IS JOHN WAGNER. I AGREE.

9 CHAIRMAN LO: BOB.

10 MR. KLEIN: YEAH. I'M LISTENING TO THE
11 EXPERTS AND INDIVIDUALS WITH A GREAT DEAL MORE
12 KNOWLEDGE THAN I HAVE, SO I DON'T HAVE ANY SEPARATE
13 COMMENTS, I THINK, ON THIS ISSUE.

14 CHAIRMAN LO: OKAY. MEMBERS OF THE PUBLIC.
15 I KNOW SUSAN FOGEL IS ON THE CALL, AND ACTUALLY YOUR
16 COMMENTS HAVE BEEN VERY HELPFUL THROUGHOUT THIS PROCESS
17 ON THIS ISSUE. IF YOU AND ANYONE ELSE ON THE CALL WHO
18 I HAVEN'T MENTIONED WANT TO ALSO SPEAK UP, I'D LIKE TO
19 MAKE SURE WE'VE HEARD FROM EVERYONE.

20 MS. FOGEL: THANK YOU. I HOPE YOU ALL GOT A
21 COPY OF OUR COMMENTS. AND, YOU KNOW, I THINK THAT
22 EVERYTHING WE HAVE EXPRESSED IS BEING -- HAS BEEN
23 ALREADY EXPRESSED. WE THINK THAT OPTION 3 IS THE ONLY
24 WAY TO GO. I THINK JEFF'S POINT ECHO OURS. THE
25 FERTILITY INDUSTRY IS PRETTY MUCH SELF-REGULATING, AND

1 THERE'S NO REASON TO CROSS THIS LINE. I THINK THAT
2 YA'LL MADE A BIG COMMITMENT TO THE PEOPLE OF CALIFORNIA
3 THAT MONEY WOULDN'T BE ON THE TABLE IN THIS PROCESS;
4 AND OPENING THE DOOR TO IT WOULD REALLY, WE THINK, BE
5 VERY DAMAGING TO WOMEN AND TO THE RESEARCH PROCESS. SO
6 WE'RE HAPPY TO HEAR THAT EVERYONE CONCURS.

7 CHAIRMAN LO: OKAY. GOOD. ANY OTHER
8 COMMENTS? SOUNDS LIKE THERE'S A VERY STRONG
9 PREFERENCE. ACTUALLY I'M NOT SURE I HEARD ANYONE NOT
10 AGREE WITH -- ACTUALLY, GEOFF, WHY DON'T WE ACTUALLY
11 TAKE A FORMAL VOTE IF WE STILL HAVE A QUORUM?

12 MR. LOMAX: I BELIEVE WE HAVE A QUORUM, SO WE
13 MIGHT AS WELL. IT'S ALWAYS NICE TO HAVE A VOTE. SO --

14 CHAIRMAN LO: GO THROUGH BECAUSE I THINK IT
15 WOULD BE HELPFUL TO THE ICOC TO SAY NOT ONLY THAT WE
16 DELIBERATED, AND I THINK THE REASONS THAT YOU'VE ALL
17 ARTICULATED, I THINK, ARE VERY GOOD, WELL THOUGHT
18 THROUGH. SO YOU WANT TO JUST GO THROUGH A FORMAL ROLL
19 CALL.

20 MR. LOMAX: COULD YOU ACTUALLY CALL A
21 SPECIFIC QUESTION?

22 CHAIRMAN LO: OKAY. WOULD SOMEONE LIKE TO
23 MOVE THAT WE ADOPT OPTION 3 AS THE PROVISIONS IN THE
24 MES STANDARDS TO BE RECOMMENDED TO THE ICOC?

25 MS. CHARO: SO MOVED.

1 CHAIRMAN LO: OKAY. SECOND?
2 DR. EGGAN: SECOND.
3 CHAIRMAN LO: OKAY. DO YOU NEED TO ACTUALLY
4 KNOW WHO MOVED AND SECONDED? IT WAS ALTA AND KEVIN, I
5 BELIEVE.
6 MR. LOMAX: THANK YOU FOR THE RECORD. THAT'S
7 HELPFUL.
8 CHAIRMAN LO: OKAY. AND, GEOFF, IF YOU OR
9 SOMEONE THERE COULD JUST DO A FORMAL ROLL CALL.
10 MR. LOMAX: WITH PLEASURE. MARCY FEIT.
11 MS. FEIT: I APPROVE.
12 MR. LOMAX: BOB KLEIN.
13 MR. KLEIN: YES.
14 MR. LOMAX: JEFF SHEEHY.
15 MR. SHEEHY: YES.
16 MR. LOMAX: ALTA CHARO.
17 MS. CHARO: YES.
18 MR. LOMAX: BERNIE LO.
19 CHAIRMAN LO: YES.
20 MR. LOMAX: PAT KING.
21 MS. KING: YES.
22 MR. LOMAX: KEVIN EGGAN.
23 DR. EGGAN: YES.
24 MR. LOMAX: ANN KIESSLING.
25 DR. KIESSLING: YES.

1 MR. LOMAX: JEFFREY KORDOWER. ROBERT TAYLOR.
2 DR. TAYLOR: YES.
3 MR. LOMAX: JOHN WAGNER.
4 DR. WAGNER: YES.
5 MR. LOMAX: IS THERE ANYONE I MISSED WHO MAY
6 HAVE JOINED THE CALL?
7 CHAIRMAN LO: OKAY. GREAT. THANKS VERY
8 MUCH. DID PAT VOTE?
9 MR. LOMAX: YES.
10 CHAIRMAN LO: YES, SHE DID. OKAY, GOOD.
11 THANK YOU ALL. I APPRECIATE A VERY LUCID AND
12 THOUGHTFUL AND VERY BRIEF DISCUSSION ACTUALLY. THAT
13 REALLY IS THE MAIN ISSUE WE HAD WANTED TO TALK ABOUT.
14 AND THIS DEGREE OF CLARITY IS WONDERFUL. I REALLY ALSO
15 APPRECIATE THE DISCUSSION THAT ANN AND ROB TAYLOR AND
16 OTHERS, KEVIN AND OTHERS ENTERED INTO. AND I THINK WE
17 ARE -- I JUST WANT TO SAY THAT WE ARE COMMITTED TO
18 PROTECTING WOMEN FROM OVERZEALOUS SORT OF HORMONAL
19 MANIPULATIONS OR RETRIEVAL PROCEDURES, AND THAT WE WILL
20 LOOK AT THE CDC GUIDELINES THAT ANN WILL DIRECT US TO.
21 AND AS ZACH POINTED OUT, I THINK THIS MEETING IN
22 SEPTEMBER, MY OWN VIEW IS I THINK THIS WILL BE A VERY
23 IMPORTANT AND USEFUL MEETING. SO BRINGING TOGETHER THE
24 BEST THINKING AND WE MAY WELL WANT TO COME BACK AND ADD
25 SOMETHING. AS SHERRY LANSING ALWAYS POINTS OUT, THIS

1 IS A WORK IN PROGRESS. AND I THINK IT IS IMPORTANT TO
2 GET ONE SET OF FINAL STANDARDS ACCEPTED AND PUT THROUGH
3 THE OAL PROCESS, BUT THERE'S CERTAINLY NOTHING TO KEEP
4 US FROM ADDING ANOTHER PROVISION TO FURTHER STRENGTHEN
5 HOW WE PROTECT WOMEN WHO ARE VOLUNTEERING TO UNDERGO A
6 PROCEDURE TO DONATE FOR RESEARCH. OUR THANKS TO ZACH
7 AND BOB AND TO THE NAS FOR PUTTING TOGETHER THIS
8 MEETING.

9 ANY OTHER ISSUES THAT WE WANT TO TALK ABOUT?

10 DR. TAYLOR: BERNIE, THIS IS ROB TAYLOR.
11 JUST GOING TO MAKE A COMMENT TO THAT LAST REMARK THAT
12 YOU MADE. THE GREATEST RISK FOR OVARIAN
13 HYPERSTIMULATION SYNDROME IS PREGNANCY. I THINK THAT,
14 YOU KNOW, CDC GUIDELINES, WHICH ARE REALLY DESIGNED FOR
15 WOMEN UNDERGOING IVF FOR THE PURPOSE OF BECOMING
16 PREGNANT, REALLY THERE ARE GOING TO BE DIFFERENT
17 ISSUES. AND I THINK THIS IOM MEETING IS GOING TO BE
18 EXTREMELY IMPORTANT IN TERMS OF IDENTIFYING THOSE
19 SPECIAL RISKS WHICH, IN MY VIEW, ARE ACTUALLY DECREASED
20 ALREADY FROM THE WOMEN UNDERGOING PREGNANCY THERAPY.
21 IT REALLY IS A DIFFERENT SET OF PATIENTS. THEY'RE NOT
22 GOING TO BE SEEING THE EMBRYO AND SEEING THE HCG AND
23 BEING AT RISK FOR THE FULL-BLOWN HYPERSTIMULATION
24 SYNDROME. SO I THINK YOU'RE RIGHT. WE DO HAVE TO HAVE
25 SEPARATE GUIDELINES FOR THAT SETTING.

1 CHAIRMAN LO: GOOD. AND, AGAIN, I THINK --

2 DR. EGGAN: AND ALSO THIS IS KEVIN, AND I
3 WOULD ADD TO THAT BY SAYING THAT IN LINE WITH THAT IT'S
4 PROBABLY NOT OUT OF LINE TO MANDATE THAT THERE BE SOME
5 SORT OF EXIT INTERVIEW OR ASSURANCE THAT THERE HASN'T
6 BEEN PREGNANCY DUE TO UNPROTECTED SEX AFTER THE
7 DONATION, WHICH COULD DRAMATICALLY EXACERBATE THE
8 SITUATION.

9 CHAIRMAN LO: YES. I THINK ROB OR SOMEONE IN
10 ONE OF OUR PREVIOUS MEETINGS POINTED OUT HOW THAT DOES
11 HAPPEN EVEN IN A CLINICAL SITUATION WITH OOCYTE DONORS.
12 AND IT CLEARLY WOULD BE SOMETHING WE WOULD WANT VERY
13 MUCH TO PREVENT IN THE RESEARCH SETTING. OKAY.

14 WELL, I THINK, AGAIN, AS ZACH POINTED OUT,
15 THIS WILL BE WEBCAST. AND I WOULD ENCOURAGE ALL OF US,
16 IT'S IN SAN FRANCISCO, SO I LOVE THAT, AND THOSE OF YOU
17 WHO CAN COME, I THINK IT WOULD BE A MOST INTERESTING
18 MEETING AND I THINK AFFORD THE OPPORTUNITY FOR A LOT OF
19 INFORMAL DISCUSSIONS WITH THE EXPERTS FROM AROUND THE
20 COUNTRY. SO --

21 DR. HALL: LET ME JUST SAY THAT THE ACTUAL
22 ATTENDANCE AT THE MEETING IS GOING TO BE LIMITED TO
23 ABOUT 75 IN ORDER TO HAVE OPTIMAL DISCUSSION. AND THE
24 IOM WILL BE MAKING THE CHOICE AMONG THOSE WHO APPLY.
25 AND THE ATTEMPT WILL BE TO HAVE BY AND LARGE PEOPLE WHO

1 CAN CONTRIBUTE SCIENTIFICALLY TO THE DISCUSSION; THAT
2 IS, WHO ARE EITHER IN THE FIELD OR HAVE PUBLISHED OR
3 ARE EXPERT, BUT I THINK THERE WILL BE SOME ROOM FOR
4 OTHERS AS WELL.

5 CHAIRMAN LO: WELL, I GUESS --

6 DR. HALL: EVERYBODY CAN -- EVERYBODY WILL BE
7 ABLE TO FOLLOW IT BY WEBCAST.

8 CHAIRMAN LO: I GUESS THE OTHER QUESTION,
9 ZACH, THIS IS REALLY GETS TO A LOGISTICS DETAIL, IS IT
10 POSSIBLE TO SORT OF ATTEND IN PERSON, BUT NOT SAY
11 ANYTHING IN THE DISCUSSION, BUT TO HAVE THE OPPORTUNITY
12 PRESUMABLY OF TALKING TO PEOPLE AT BREAKS AND AFTER THE
13 MEETING?

14 DR. HALL: NOT THE WAY IT'S SET UP.

15 CHAIRMAN LO: OKAY. I WITHDRAW MY EARLIER
16 COMMENT OFFERING TO ENCOURAGE YOU PEOPLE TO GO THERE.

17 DR. HALL: WE ENCOURAGE PEOPLE TO APPLY, AND
18 THE ICOC WILL MAKE SOME SORT OF DECISION -- I MEAN,
19 SORRY, NOT THE ICOC. THE IOM WILL MAKE SOME SORT OF
20 DECISION ABOUT WHO CAN COME AND NOT IN ORDER TO GET --
21 THE WHOLE IDEA IS TO HAVE A NOT TOO LARGE GROUP AND TO
22 HAVE LIVELY DISCUSSION.

23 CHAIRMAN LO: ABSOLUTELY. I COULDN'T AGREE
24 MORE. I JUST WANT TO POINT OUT AGAIN THE WAY ZACH AND
25 THE IOM HAVE SET THIS UP IS THAT, ALTHOUGH CIRM IS THE

1 ONE SPONSORING THIS, WE ARE NOT ORGANIZING THE MEETING.
2 WE'RE SORT OF GIVING IT TO THE IOM, AND THAT ARM'S
3 LENGTH RELATIONSHIP HELPS TO ASSURE THAT IT'S REALLY AS
4 OBJECTIVE AND UNBIASED AS POSSIBLE, THAT WE DON'T HAVE
5 CONTROL OVER THE SPEAKERS. IT'S THE IOM PEOPLE WHO ARE
6 SELECTED BY A PROCESS THAT VERY CAREFULLY LOOKS AT BIAS
7 AND PARTIALITY, SO IT REALLY GOES A LONG WAY TO
8 ASSURING THAT THIS REALLY IS THE BEST AND MOST
9 OBJECTIVE SORT OF STATE-OF-THE-ART EVIDENCE AND WILL BE
10 PUBLISHED AS A WORKSHOP REPORT. IT SHOULD BE VERY
11 USEFUL.

12 DR. EGGAN: AND HOW DO WE APPLY TO BE ABLE TO
13 ATTEND THAT?

14 DR. HALL: WELL, WE'RE STILL -- WE HAVE NOT
15 DECIDED ON THOSE TWO DATES, AND WE NEED TO DO THAT
16 FIRST. AND IT WILL BE POSTED. AS SOON AS WE DO, IT
17 WILL BE POSTED ON OUR WEBSITE.

18 CHAIRMAN LO: MAYBE WHAT YOU COULD DO, GEOFF,
19 IS AS SOON AS WE KNOW THAT, LET THOSE OF US ON THE
20 COMMITTEE, PARTICULARLY, I THINK, PEOPLE LIKE KEVIN AND
21 ROB AND ANN KIESSLING, WHO MAY, IN FACT, FILL A SLOT
22 FOR THEIR TECHNICAL EXPERTISE IF THEY WANT TO ATTEND.
23 YOU KNOW, MAKE SURE THAT THEIR APPLICATION IS SUBMITTED
24 IN A TIMELY FASHION.

25 MR. LOMAX: ABSOLUTELY.

1 CHAIRMAN LO: ASSUMING THEY WANT TO.

2 DR. KIESSLING: OH, I THINK IT'S IMPORTANT.

3 CHAIRMAN LO: OKAY. ALL RIGHT. GREAT. ANY
4 OTHER ISSUES FOR DISCUSSION?

5 MS. FOGEL: IS THERE PUBLIC COMMENT FOR A
6 SECOND?

7 CHAIRMAN LO: YES, PLEASE. IS THIS SUSAN?

8 MS. FOGEL: YEAH. THIS IS SUSAN. I WANT TO
9 GO BACK TO THE ISSUES THAT YOU WERE DISCUSSING A FEW
10 MINUTES AGO ABOUT THE RISKS. ONE OF THE THINGS THAT WE
11 AND THE CENTER FOR GENETICS AND SOCIETY AND THE
12 FOUNDATION FOR TAXPAYER AND CONSUMER RIGHTS HAD
13 COMMENTED ON IN A PREVIOUS ITERATION OF THE REGULATIONS
14 WAS DATA COLLECTION. AND UNFORTUNATELY THOSE COMMENTS
15 WERE REJECTED. THERE IS A DATA COLLECTION REQUIREMENT
16 IN SB 1260, BUT, OF COURSE, THAT DOESN'T APPLY TO CIRM.
17 AND I THINK THAT IT REALLY, BECAUSE OF ALL THE -- YOU
18 DO HAVE LIMITED MONITORING AND ENFORCEMENT CAPABILITY.
19 AND IF YOU'RE NOT GOING TO MAKE DATA REQUESTS ABOUT
20 ADVERSE AND OTHER OUTCOMES, NOBODY ELSE IS ASKING FOR
21 THIS INFORMATION. MOST OF THE CDC INFORMATION TO
22 DATE -- I MEAN THEY MAY CHANGE IT, BUT TO DATE IT'S
23 MOSTLY ABOUT BIRTH OUTCOMES. AND SO WE DON'T HAVE GOOD
24 DATA.

25 AND IF YOU'RE GOING TO WANT TO GO BACK AND

1 MAKE SURE THAT WOMEN AREN'T BEING HARMED, THAT RISKS
2 ARE BEING MINIMIZED, YOU HAVE ABSOLUTELY NO WAY TO KNOW
3 THAT IF YOU DON'T DEMAND SOME FAIRLY RIGOROUS DATA
4 COLLECTION.

5 DR. KIESSLING: I THINK THAT'S GOING TO BE
6 HANDLED AT THE LEVEL OF THE INSTITUTIONAL REVIEW BOARD.

7 DR. HALL: WELL, I THINK, ALSO, ONE OF THE
8 QUESTIONS -- WE HAVE THREE QUESTIONS FOR THE UPCOMING
9 MEETING. ONE IS WHAT DATA DO WE HAVE? WHAT IS THE
10 BEST INFORMATION WE HAVE ABOUT THE MEDICAL RISK TO EGG
11 DONORS? WHAT INFORMATION, NO. 1? NO. 2, WHAT
12 INFORMATION DO WE NEED? AND THEN, NO. 3, HOW CAN WE
13 MITIGATE RISK? AND SO I THINK WE'RE VERY AWARE OF
14 THAT, AND I THINK THERE'S SEVERAL WAYS TO HANDLE IT.
15 ONE WOULD BE TO PUT IT IN THE RFA. ONE WOULD BE TO
16 COMMISSION AND PAY FOR STUDIES DIRECTLY. AND SO I
17 THINK IT'S AN ISSUE WE ARE VERY CONCERNED WITH AND WILL
18 BE VERY ATTENTIVE TO. AND WE DEFINITELY WANT TO TAKE
19 ADVANTAGE OF THE OPPORTUNITY TO GATHER INFORMATION
20 ABOUT THIS IN THE COURSE OF WHATEVER RESEARCH WE
21 SPONSOR.

22 DR. EGGAN: THIS IS KEVIN EGGAN. I'D LIKE TO
23 RESPOND TOO, AND I'D LIKE TO ECHO HOW IMPORTANT I THINK
24 THIS ISSUE IS, BUT I'D ALSO LIKE TO AMPLIFY ANN'S
25 STATEMENTS. AND THAT IS THAT ANY OF THE TYPES OF

1 EXPERIMENTS THAT WOULD INVOLVE WOMEN DIRECTLY
2 PARTICIPATING IN THE RESEARCH BY DONATING MATERIAL AS
3 HUMAN SUBJECTS WILL BE VERY SPECIFICALLY COVERED BY
4 INSTITUTIONAL REVIEW BOARD AUTHORITY. AND THERE ARE
5 RULES OF LAW WHICH PRESCRIBE THE REPORTING WHICH WOULD
6 HAVE TO BE DONE IN THE CASE OF ADVERSE EVENT. SO I
7 THINK THAT INFORMATION IS GOING TO BECOME AVAILABLE
8 THROUGH THAT MECHANISM, THAT THERE IS ALREADY INDEED IN
9 PLACE A MECHANISM FOR ENSURING THAT WE COULD OBTAIN
10 THAT INFORMATION.

11 MS. FOGEL: ONLY TO THE EXTENT THAT THOSE
12 WOMEN ARE CONSIDERED HUMAN SUBJECTS, WHICH I REALIZE IS
13 AN ISSUE OF GREAT CONVERSATION AROUND THE COUNTRY AS
14 TO -- CERTAINLY OUR POSITION HAS BEEN THAT ALL WOMEN
15 WHO PARTICIPATE OUGHT TO BE CONSIDERED HUMAN SUBJECTS,
16 BUT COUNTERARGUMENTS HAVE BEEN MADE THAT, YOU KNOW,
17 WHEN THEY DON'T MEET THE FEDERAL -- WHEN THE RESEARCH
18 DOESN'T MEET THE FEDERAL STANDARDS, YOU KNOW,
19 ANONYMIZED, ETC., THAT THESE WOMEN WILL NOT BE
20 CONSIDERED HUMAN SUBJECTS. YOU KNOW, MILDRED CHO AND
21 DAVID MAGNUS HAVE WRITTEN ABOUT THIS. LIKE WHERE DO
22 THESE WOMEN FALL?

23 SO TO THE EXTENT THEY ARE HUMAN SUBJECTS,
24 YES, BUT THERE STILL COULD BE A LOOPHOLE OR A GAP --

25 MS. CHARO: ACTUALLY --

1 MS. FOGEL: -- FOR WOMEN WHO AREN'T TREATED
2 THAT WAY.

3 MS. CHARO: IF I MAY, THE HUMAN SUBJECTS
4 REGULATIONS MAKE IT VERY CLEAR THAT EVERY PERSON WHO'S
5 AN EGG DONOR MUST BE A HUMAN SUBJECT BECAUSE IT
6 INVOLVES AN ACTUAL INTERVENTION. THE ONLY GAP THAT CAN
7 OCCUR IS A GAP FOR COUPLES THAT ARE DONATING SURPLUS
8 EMBRYOS THAT ARE COMPLETELY ANONYMIZED. BUT EGG DONORS
9 CANNOT FALL OUTSIDE THE FEDERAL RULES.

10 IN ADDITION, WE'VE EXTENDED HUMAN SUBJECTS
11 PROTECTIONS TO EVERYBODY EVEN IF THE FEDERAL RULES
12 DON'T APPLY, SO THAT COVERS THE COUPLES DONATING
13 EMBRYOS AS WELL.

14 CHAIRMAN LO: FOR CIRM-FUNDED RESEARCH.

15 MS. CHARO: YES.

16 CHAIRMAN LO: ABSOLUTELY. THE OTHER THING I
17 WANT TO POINT OUT, I MEAN PEOPLE NOTED THE INTERACTION
18 BETWEEN OUR OVERSIGHT AND IRB'S, BUT IT'S ALSO
19 IMPORTANT THAT, THROUGH THE GRANTS MECHANISMS, THAT
20 THERE ARE REPORTS TO BE SUBMITTED BY CIRM GRANTEES.
21 AND CIRM ALSO HAS THE RIGHT TO REQUIRE, YOU KNOW,
22 AUDITS AS NEEDED AND ADDITIONAL INFORMATION. SO
23 CERTAINLY IF AFTER THIS CONFERENCE THERE'S A SPECIFIC
24 PLAN FOR COLLECTING ADDITIONAL INFORMATION, AGAIN, THAT
25 CAN BE EASILY ADDED TO THE EXISTING FRAMEWORK.

1 AGAIN, WE'RE -- WE WANT TO MAKE SURE THAT --
2 WE HAVE TO WRITE REGULATIONS THAT ARE ACCEPTABLE TO THE
3 OAL, WHICH MEANS THAT PEOPLE WHO ARE BEING REGULATED
4 NEED TO KNOW WHAT INFORMATION NEEDS TO BE COLLECTED,
5 WHAT THEY NEED TO DO TO BE IN COMPLIANCE. AND I THINK
6 THAT ONE OF THE CONCERNS THAT'S BEEN RAISED IS SORT OF
7 THE DEFINITIONS OF VARIOUS TERMS, AND THIS SEGMENT
8 SHOULD BE DISCUSSED AT THE NAS -- THE IOM CONFERENCE.
9 YOU KNOW, THE DEFINITION OF OVARIAN HYPERSTIMULATION
10 SYNDROME MAY VARY FROM ONE SITE TO ANOTHER.

11 THIS, AGAIN, IS AN IMPORTANT POINT AND THIS
12 ISN'T -- AND WHAT WE DO IN THESE NAS FINAL REGULATIONS
13 IS NOT BY ANY MEANS MEANT TO BE THE FINAL WORD.

14 MR. SHEEHY: THIS IS JEFF SHEEHY. I ACTUALLY
15 THINK THAT ZACH HAD A GREAT IDEA IN ISSUING AN RFA AND
16 ACTUALLY HAVING SOMEBODY STUDY THIS. IT'S ALMOST AS IF
17 THE -- YOU KNOW, JUST SIMPLY COLLECTING THE DATA MAY
18 NOT ACTUALLY GIVE US INFORMATION WE WANT, AND ACTUALLY
19 MAKING A FORMAL RESEARCH PROJECT, I THINK, WOULD
20 PROBABLY GIVE US MORE INFORMATION.

21 CHAIRMAN LO: LIFE GOING ON AT GRADY MEMORIAL
22 HOSPITAL. AGAIN, THIS IS AGAIN CONTINGENT ON THE MONEY
23 FROM PROP 71 REALLY COMING THROUGH SO THAT THE PLAN
24 ZACH AND HIS STAFF ARE DEVELOPING FOR PRIORITIES FOR
25 ACTUAL PROJECTS GET DEVELOPED. AND, AGAIN, AS JEFF

1 SAYS, THIS COULD WELL BE SOMETHING THAT IS IMPORTANT
2 ENOUGH THAT WE WOULD -- THAT THE CIRM MAY CHOOSE TO
3 ACTUALLY REQUEST THAT IT BE CARRIED OUT.

4 MR. KLEIN: BERNIE ON THAT NOTE, THIS IS BOB
5 KLEIN, I HAVE TO LEAVE THE CALL. I'M GOING OUT TO --
6 I'M CLOSING A MAJOR PORTION OF ADDITIONAL MONEY FOR
7 CIRM. SO EXCEPT FOR THAT REASON I WOULDN'T BE GOING
8 OFF THIS CALL. IT LOOKS LIKE IT'S GOING TO BE
9 IMPORTANT TO YOU TO KNOW THAT WHAT WE'RE TALKING ABOUT
10 IS HAPPENING IN THE NEAR FUTURE.

11 CHAIRMAN LO: OKAY. WELL, THANKS. BOB, I
12 THINK ALL OF US REALLY APPRECIATE WHAT YOU AND YOUR
13 STAFF HAVE DONE TO KIND OF IMPLEMENT THIS INTO REALITY.
14 IT'S NOT BEEN AN EASY TASK ACTUALLY HAVING THE MONEY
15 APPEAR, AND THERE'S A LOT OF WORK THAT WE DON'T ON THE
16 SWG SEE THAT I KNOW HAS BEEN VERY IMPORTANT. IT'S
17 GREAT THAT IT'S ACTUALLY HAPPENING.

18 MR. KLEIN: AN ADDITIONAL 30 MILLION THAT'S
19 MOVING TO CLOSURE VERY, VERY PREDICTABLY. WE THANK YOU
20 BECAUSE WITHOUT YOUR WORK WE WOULDN'T BE ABLE TO SPEND
21 IT EFFECTIVELY WITH THE RIGHT ACCOUNTABILITY, SO IT'S A
22 CRITICAL ELEMENT IN MAKING THIS ALL WORK.

23 DR. KIESSLING: IT'S ALWAYS GREAT TO HELP
24 PEOPLE SPEND MONEY ON RESEARCH, BOB.

25 CHAIRMAN LO: GOOD RESEARCH, IMPORTANT

1 RESEARCH.

2 MR. KLEIN: THANK YOU. I THINK THE STANDARDS
3 ARE EXTRAORDINARILY WELL THOUGHT OUT. I WILL GET OFF
4 NOW, BUT THANK YOU AGAIN.

5 CHAIRMAN LO: OKAY. GREAT. THANKS, BOB.

6 OKAY. SINCE WE HAVE COMPLETED WHAT WAS SORT
7 OF WE HAD INFORMALLY HOPED FOR THE AGENDA, I THINK AT
8 THIS POINT, IF ZACH OR MAYBE ALTA, IF YOU'VE BEEN
9 FOLLOWING, YOU WANT TO SORT OF JUST QUICKLY LET US KNOW
10 WHAT'S HAPPENING IN WASHINGTON WITH THE THREE MEASURES.
11 AND, ALTA, YOUR SITE, WEBSITE, SAID THE VETO WAS LIKELY
12 TO HAPPEN AT 2 P.M. THIS AFTERNOON.

13 MS. CHARO: THAT WAS THE LAST PREDICTION. I
14 WAS JUST CHECKING. THERE HASN'T BEEN ANY UPDATE, SO
15 THERE'S GOING TO BE COMPETING PRESS EVENTS. REPORTERS
16 WILL HAVE A GROUP OF SENATORS ALONG WITH PATIENTS, AND
17 THE PRESIDENT IS PLANNING A VETO SURROUNDED BY PEOPLE
18 WHO HAVE ADOPTED FROZEN EMBRYOS, THE SO-CALLED
19 SNOWFLAKE CHILDREN, SO THERE WILL BE COMPETING EVENTS,
20 AND THE VETO IS EXPECTED AROUND 2 P.M.

21 IN ADDITION, YOU MAY RECALL THERE WERE TWO
22 OTHER BILLS THAT WERE CAPPED BY THE SENATE. ONE IS THE
23 SO-CALLED FETAL FARMING BILL, AND THE HOUSE HAS NOT
24 TAKEN ACTION ON THAT TO MY KNOWLEDGE. THIS BILL IS
25 ACTUALLY A LITTLE BIT BESIDE THE POINT BECAUSE IT

1 PROHIBITS SOMETHING THAT NOBODY IS DOING OR PLANNING TO
2 DO. AND THE OTHER WAS THE SANTORUM BILL TO PROMOTE NIH
3 RESEARCH INTO SO-CALLED ALTERNATIVE SOURCES FOR
4 EMBRYONIC STEM CELLS, THINGS LIKE THE DISABLED EMBRYOS
5 AND THE USE OF THE DEAD EMBRYOS. THAT BILL DID
6 APPARENTLY GO TO THE HOUSE YESTERDAY, AND THE HOUSE
7 VOTED IT DOWN UNDER THE RULE WHICH REQUIRED A
8 TWO-THIRDS VOTE BY THE HOUSE. THAT WAS REALLY MORE
9 ABOUT POLITICS.

10 THE CONCERN HAD BEEN THAT IF THAT BILL WERE
11 PASSED, IT WOULD GIVE PEOPLE A CHANCE TO SAY THAT THEY
12 HAD VOTED FOR STEM CELL RESEARCH WHEN, IN FACT, THEY
13 HAD ACTUALLY VOTED AGAINST THE MAIN BILL, WHICH WAS HR
14 810. AND IN ADDITION, THE NIH ALREADY HAS THE
15 AUTHORITY TO FUND THAT RESEARCH, ACCORDING TO JIM
16 BATTEY'S TESTIMONY BEFORE CONGRESS.

17 SO AT THIS POINT WE'RE LOOKING FOR THE VETO
18 AND PROBABLY AT SOME POINT HOUSE ACTION ON THE
19 SO-CALLED FETAL FARMING BILL.

20 CHAIRMAN LO: GOOD. THANKS. ZACH, DO YOU
21 HAVE ANYTHING YOU WANT TO ADD TO THAT?

22 MR. LOMAX: ZACH HAS HAD TO STEP OUT, BUT I
23 THINK --

24 CHAIRMAN LO: OKAY. I THINK, ALTA, YOU'VE
25 BEEN REALLY RIGHT ON TOP OF THIS. OKAY. WELL, IF

1 THERE'S NOTHING ELSE THAT PEOPLE WANT TO BRING UP, I
2 WOULD BE GLAD TO ENTERTAIN A MOTION FOR ADJOURNMENT AND
3 BEST WISHES TO ALL OF YOU FOR THE REST OF THE SUMMER.

4 MR. REED: I HAVE A COMMENT, QUESTION.

5 MR. LOMAX: WE HAVE ONE COMMENT, SORRY, FROM
6 THE CIRM SITE. DON REED HERE.

7 CHAIRMAN LO: OKAY. PLEASE. HI. I DIDN'T
8 REALIZE YOU WERE THERE.

9 MR. REED: NO PROBLEM. ALTA, I HAD HEARD
10 THAT THE HOUSE MAY RE-VOTE ON THE SANTORUM ALTERNATIVE
11 METHOD. DO YOU KNOW ANYTHING ABOUT THAT?

12 MS. CHARO: I DON'T. THAT'S VERY
13 INTERESTING, BUT -- WHERE DID YOU HEAR THAT?

14 MR. REED: HEARD IT THIS MORNING ON THE WEB
15 SOMEWHERE. YOU DON'T KNOW ANYTHING ABOUT IT -- SO YOU
16 HEARD THAT TOO?

17 MS. CHARO: I'LL TAKE A LOOK. I'LL TAKE A
18 LOOK.

19 MR. REED: OKAY. THANK YOU.

20 MS. CHARO: YOU KNOW, AGAIN, IT'S MORE ABOUT
21 POLITICAL POSTURING SINCE THE NIH ALREADY HAS THE
22 AUTHORITY ON THE FUNDING TO DO EXACTLY THE SAME WORK
23 THAT'S OUTLINED IN THAT BILL.

24 DR. PETERS: ALTA, WILL THERE BE ANY
25 IMPLICATIONS FOR US IN CALIFORNIA, OR DO YOU THINK IT'S

1 VIRTUALLY IRRELEVANT?

2 CHAIRMAN LO: IS THIS TED? HI, TED.

3 MS. CHARO: IT'S IRRELEVANT IN TERMS OF
4 ACTUAL ON-THE-GROUND FUNDING BECAUSE, ASSUMING THE
5 PRESIDENT VETOES, NO NEW MONEY COMES OUT, AND
6 POLITICALLY THERE ARE NO CANDIDATES AT RISK IN
7 CALIFORNIA WHOSE VOTES WOULD BE SIGNIFICANT IN THEIR
8 OWN ELECTORAL CAMPAIGNS THAT WE CAN TELL. SO IT'S --
9 THE REAL ACTION HAS NOW MOVED TO THE CONGRESSIONAL AND
10 SENATE RACES FOR NOVEMBER. AND THE WAY IN WHICH THE
11 VOTES WILL PLAY OUT, FOR EXAMPLE, JIM TALENT FROM
12 MISSOURI, WHO'S IN A VERY CLOSE RACE WITH A LOT OF STEM
13 CELL ISSUES THERE, VOTED AGAINST HR 810. SO WE CAN
14 PREDICT. WE'LL SEE THINGS LIKE THAT.

15 ONE DEMOCRAT WHO VOTED AGAINST 810 IS THE
16 SENATOR FROM NEBRASKA WHO'S ALSO IN A VERY TIGHT RACE;
17 AND NEBRASKA, AS YOU KNOW, HAS HAD A LONG HISTORY WHICH
18 IS DEALING WITH FETAL TISSUE RESEARCH OF HIGH
19 CONTROVERSY. SO THAT MAY INDICATE WHY HE WAS VOTING
20 THE WAY HE WAS.

21 DR. PETERS: WHERE IS THE BROWNBACK
22 ANTICHIMERISM MEASURE AT THIS PARTICULAR STAGE? IS
23 THAT A DEAD LETTER, OR IS IT INCORPORATED IN ANY OF
24 THIS?

25 MS. CHARO: IT HAS NEVER COME OUT OF

1 COMMITTEE, SO THE BROWNBACK ANTICLONING BILL, WHICH
2 WOULD CRIMINALIZE CLONING NATIONALLY, HAS NEVER GOTTEN
3 A VOTE. THEY DON'T APPEAR YET TO HAVE THE VOTES TO
4 PASS IT TO ACCOMPANY THE HOUSE VOTE FROM A COUPLE OF
5 YEARS AGO. AND THE CHIMERA BILL AND THE ANTIPATENTING
6 OF EMBRYOS BILLS NEVER CAME TO THE FLOOR. THEY
7 NEVER -- I DON'T BELIEVE THEY EVER CAME OUT OF
8 COMMITTEE.

9 DR. PETERS: THANKS.

10 MR. LOMAX: TED, WHILE WE HAVE YOU ON THE
11 LINE, THIS IS GEOFF LOMAX, THE COMMITTEE MOVED A MOTION
12 TO APPROVE -- INCORPORATE THE THIRD OPTION LANGUAGE IN
13 THE REGULATIONS. DO YOU WANT TO REGISTER AN OPINION ON
14 THAT, A YES-OR-NO VOTE?

15 DR. PETERS: I'LL GIVE YOU A YES.

16 MR. LOMAX: OKAY. THANK YOU. JUST FOR THE
17 RECORD. LIKE TO ALSO THANK EVERYONE FOR --

18 CHAIRMAN LO: I GUESS LET'S VOTE ON THE
19 MEASURE FOR ADJOURNMENT, EVERYONE.

20 MR. LOMAX: I'VE GOT A VOTE.

21 CHAIRMAN LO: OKAY. THANK YOU ALL VERY MUCH
22 AND HAVE A GREAT END OF THE SUMMER. EVERYONE TAKE A
23 REAL VACATION.

24 MR. LOMAX: AND THANKS FOR MAKING TIME FOR
25 THIS CALL. WE KNOW IT WAS A REAL CHALLENGE FOR YOU ALL

1 AND REALLY APPRECIATE THE NUMBER OF PEOPLE WE GOT ON
2 THIS ONE. THANKS AGAIN.

3 CHAIRMAN LO: THANKS AGAIN. BYE-BYE.

4 (THE MEETING WAS THEN ADJOURNED.)

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

REPORTER'S CERTIFICATE

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE PROCEEDINGS BEFORE THE SCIENTIFIC AND MEDICAL ACCOUNTABILITY STANDARDS WORKING GROUP OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD AT THE LOCATION INDICATED BELOW

CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
210 KING STREET
SAN FRANCISCO, CALIFORNIA
ON
JULY 19, 2006

WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE 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 S.E. BRISTOL STREET
SUITE 100
SANTA ANA HEIGHTS, CALIFORNIA
(714) 444-4100