

BEFORE THE
STANDARDS WORKING GROUP 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, NOVEMBER 22, 2010
1:30 P.M.

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

BRS FILE NO.: 88704

BARRISTERS' REPORTING SERVICE

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BARRISTERS' REPORTING SERVICE

1 NOVEMBER 22, 2010

2 1:30 P.M.

3

4

CHAIRMAN LO: WHY DON'T WE GO AHEAD AND
5 GET STARTED.

6

DR. LOMAX: AT THE MOMENT WE'RE SHORT OF A
7 QUORUM.

8

CHAIRMAN LO: SO WE CAN TAKE A SENSE OF
9 THE COMMITTEE. WHY DON'T WE FIRST -- WE'VE GOT SOME
10 NEW PEOPLE, SO LET'S INTRODUCE THEM. TIM AND PAT,
11 DO YOU WANT TO GIVE A BRIEF INTRODUCTION. I'LL JUST
12 HAVE EVERYBODY ELSE INTRODUCE THEMSELVES AS WELL.
13 TIM, YOU WANT TO JUST SAY AWARD. WE'RE DELIGHTED TO
14 HAVE YOU BOTH, AND YOU JUST WANT TO SAY A WORD ABOUT
15 WHERE YOU ARE FROM AND WHAT YOU DO.

16

DR. KAMP: MY NAME IS TIM KAMP. I'M FROM
17 THE UNIVERSITY OF WISCONSIN. I'M A CARDIOLOGIST AND
18 CARDIOVASCULAR RESEARCHER AND HAVE BEEN STUDYING
19 STEM CELLS TO UNDERSTAND CARDIAC ARRHYTHMIAS AND
20 HEART FAILURE AS WELL AS THERAPY. AND I'M ALSO
21 DIRECTOR OF THE STEM CELL CENTER HERE AT WISCONSIN.

22

23

CHAIRMAN LO: GREAT. WE'RE LOOKING
24 FORWARD TO YOUR SORT OF CLINICAL EXPERTISE AND ALSO
25 YOUR EXPERTISE WITH CLINICAL TRIALS THAT WE'RE
HOPEFULLY GOING TO GET MORE AND MORE INVOLVED WITH.

BARRISTERS' REPORTING SERVICE

1 PAT.

2 DR. TAYLOR: SURE. I WAS THERE AT THE
3 WORKSHOP EARLIER THIS YEAR. I ACTUALLY WAS THERE
4 FOR THAT. BUT FOR ANYONE ELSE, I'M DEPUTY GENERAL
5 COUNSEL AT CHILDREN HOSPITAL'S AS WELL AS HAVING A
6 MODEST ACADEMIC CAREER WRITING ABOUT STEM CELL LAW
7 AND ETHICS ABUSE. AND FULL TIME AT THE CENTER AT
8 THE LAW SCHOOL, HARVARD LAW SCHOOL, BASICALLY HAVING
9 TIME TO THINK, WRITE, AND PARTICIPATE IN TELEPHONE
10 CALLS LIKE THIS.

11 CHAIRMAN LO: OKAY. GREAT. WHY DON'T THE
12 REST OF US JUST INTRODUCE OURSELVES. I'M BERNIE LO
13 FROM UCSF. I'M GOING TO -- I CO-CHAIR THE GROUP,
14 AND I'LL SORT OF TRY AND MAKE SURE THE MEETING --
15 THE PHONE CALL RUNS ON TIME. ROB.

16 DR. TAYLOR: I'M ROB TAYLOR. I'M VICE
17 CHAIR FOR RESEARCH IN THE GYNECOLOGY AND OBSTETRICS
18 DEPARTMENT NOW AT EMORY UNIVERSITY. I HAD BEEN AT
19 UCSF, AND I HELPED KIND OF DEVELOP THE FLEDGLING
20 STEM CELL PROGRAM THERE AT THAT TIME THAT ALSO CAME
21 OUT OF OUR -- IN PART OUT OF OUR REPRODUCTIVE HUMAN
22 STEM CELL PROGRAM OUT OF OUR REPRODUCTIVE
23 ENDOCRINOLOGY AND INFERTILITY PROGRAM.

24 CHAIRMAN LO: GREAT. TED. TED PETERS.
25 MAYBE HE STEPPED OFF. JEFF.

BARRISTERS' REPORTING SERVICE

1 MR. SHEEHY: ARE YOU ON, TED?
2 DR. PETERS: I CAN WAIT. GO AHEAD.
3 CHAIRMAN LO: NO. GO AHEAD, TED. I'M
4 SORRY.

5 DR. LOMAX: MIGHT BE HAVING A BIT OF
6 TROUBLE WITH THE LINE.

7 MR. SHEEHY: I'LL GO AHEAD. I'M JEFF
8 SHEEHY. I'M ONE OF THE BOARD MEMBERS FOR THE
9 INSTITUTE, PATIENT ADVOCATE BOARD MEMBER FROM THE
10 HIV/AIDS COMMUNITY, AND I ALSO SERVE AS VICE CHAIR
11 OF THE GRANTS WORKING GROUP.

12 CHAIRMAN LO: TED, YOU HAVE YOUR PHONE
13 WORKING NOW?

14 DR. LOMAX: I'LL SEE IF WE CAN --

15 CHAIRMAN LO: ANYBODY ELSE JUST JOIN?

16 DR. LOMAX: MAYBE WE DROPPED HIS LINE.

17 CHAIRMAN LO: WE'LL TRY AND GET HIM BACK.
18 SO FIRST LET ME JUST SAY THAT SHERRY LANSING, THE
19 CO-CHAIR OF THE STANDARDS WORKING GROUP, IS UNABLE
20 TO ATTEND AND SENDS HER REGARDS. AND I WILL TELL
21 YOU HER THOUGHTS ON THE AGENDA ITEM LATER, BUT SHE
22 WELCOMES, PARTICULARLY WELCOMES THE NEW MEMBERS AND
23 SAID HI TO ALL THE OLD MEMBERS.

24 JOSE CIBELLI STEPPED DOWN FROM THE SWG.
25 AND WE'LL BE LOOKING TO REPLACE HIM WITH ANOTHER

BARRISTERS' REPORTING SERVICE

1 SCIENTIFIC MEMBER.

2 DID ANYBODY ELSE JUST JOIN?

3 DR. PETERS: THIS IS TED. I'M BACK.

4 CHAIRMAN LO: WE WERE JUST INTRODUCING
5 OURSELVES. SO YOU JUST WANT TO SAY A WORD.

6 DR. PETERS: YEAH. MY NAME IS TED PETERS.
7 AND I'M A PROFESSOR AT THE GRADUATE THEOLOGICAL
8 UNION IN BERKELEY. AND I WORK IN THE AREA OF
9 BIOETHICS AND HAVE BEEN AT THE ELBOW OF STEM CELL
10 RESEARCHERS SINCE THE FIRST ISOLATION IN 1998.

11 CHAIRMAN LO: GREAT. GREAT. GEOFF, DO
12 YOU WANT TO GIVE US SORT OF AN UPDATE ON THE CIRM
13 SCIENTIFIC WORKSHOP AND LEAD INTO THE MAIN AGENDA
14 ITEM.

15 DR. LOMAX: THANK YOU, BERNIE. AND JUST
16 TO ADD, WE HAVE JOHN ROBSON, ALAN TROUNSON, ELONA
17 BAUM, AND SCOTT TOCHER AT CIRM AT THE SITE HERE.

18 SO YOU ALL MAY RECALL IN MAY OF THIS YEAR
19 WE HAD A WORKSHOP WHERE WE DISCUSSED ISSUES RELATED
20 TO THE BANKING OF TISSUES AND STEM CELL LINES. WE
21 PUBLISHED THAT WORKSHOP REPORT AT THE END OF MAY,
22 AND YOU ALL SHOULD HAVE RECEIVED COPIES OF THAT. IF
23 NOT, IT'S AVAILABLE ON THE STANDARDS PAGE OF THE WEB
24 SITE.

25 IF YOU REMEMBER AT THE TIME, THE STANDARDS

BARRISTERS' REPORTING SERVICE

1 WORKING GROUP WAS CHARGED WITH CONSIDERATION OF
2 ISSUES RELATED TO THE BANKING AND DISTRIBUTION OF
3 HUMAN CELLS AND TISSUES. AND THEN THE FOLLOW-ON
4 WORKSHOP TO THAT WAS INTENDED TO CONSIDER THE
5 SCIENTIFIC NEED AND VALUE OF AN IPS BANK OR A TISSUE
6 BANK IN GENERAL.

7 THAT MEETING WAS ACTUALLY LAST WEEK. AND
8 THE SPEAKERS DID EMPHASIZE THE NEED TO CONSIDER
9 POLICIES GOVERNING BOTH INFORMED CONSENT, WHICH I
10 THINK WE FELT AT THE INITIAL WORKSHOP THAT THE CIRM
11 INFORMED CONSENT REQUIREMENTS WERE SUFFICIENTLY
12 ROBUST, SO WE FELT WE COULD BE RESPONSIVE AT THAT
13 LEVEL, BUT THERE WAS ALSO A LOT OF DISCUSSION ABOUT
14 BOTH OBTAINING GENOTYPIC DATA AND THEN THE
15 SUBSEQUENT DISTRIBUTION OF CELL LINES, AND ALSO BOTH
16 DISTRIBUTE LINES AND POTENTIALLY RECONTACT DONORS.

17 AGAIN, ISSUES THAT WE TOUCHED ON IN THE
18 WORKSHOP AND MAY NEED TO SORT OF RECONSIDER IF A
19 FORMAL PROPOSAL MOVES FORWARD FOR THE BANK.

20 ALAN, I DON'T KNOW IF THERE'S ANYTHING
21 YOU'D LIKE TO ADD THERE OR ANY THOUGHTS REGARDING
22 THE BANKING WORKSHOP PER SE, IF THERE'S ANYTHING AT
23 THIS TIME.

24 DR. TROUNSON: WELL, I THINK SOME OF THE
25 COMMENTS FROM MEMBERS OF THE WORKSHOP DID FOCUS ON

BARRISTERS' REPORTING SERVICE

1 THE NEED TO HAVE APPROPRIATE CONSENT. AND
2 FREQUENTLY THAT KIND OF CONSENT FOR GENERATING BASIC
3 INFORMATION DOESN'T ALWAYS GO ACROSS TO POTENTIAL
4 COMMERCIALIZATION OF MATTERS THAT ARISE OUT OF THE
5 BASIC RESEARCH AND THE POSSIBLE NEED TO UTILIZE
6 SPECIFIC CELL LINES IN A MORE GENERALIZED WAY.

7 AND SO THERE WAS A VIEW THAT IN
8 ESTABLISHING ANY KIND OF BANK, IT WOULD BE A VERY
9 GOOD IDEA TO FULLY EXPLORE THE ISSUES THAT MAY
10 RELATE TO WHAT COULD HAPPEN AS A RESULT OF THE
11 RESEARCH IN THIS AREA.

12 SO OTHERWISE IT'S SOMETIMES MORE DIFFICULT
13 TO GET BACK TO THOSE DONORS IF YOU WANT TO CLARIFY
14 SOME MATTER. SO I THINK THERE WAS A FEELING THAT
15 ANY BANK SET UP ANYWHERE, THEN IT NEEDS TO BE VERY
16 CLEAR THAT THE MATERIAL IN THE BANK IS FOR RESEARCH
17 GENERALLY AND THAT THE DONORS AGREE TO THAT, BUT
18 THERE ALSO COULD BE OTHER ELEMENTS THAT ARISE FROM
19 IT, SUCH AS COMMERCIALIZATION OF A PRODUCT THAT MAY
20 HAVE SOME RELATIONSHIP TO THAT LINE BECAUSE THAT
21 LINE WAS USED TO DISCOVER SOME IMPORTANT NEW ISSUE.

22 IT MAY BE THAT YOU COULD IDENTIFY GENES
23 THAT WERE PREDISPOSING TO A NUMBER OF CONDITIONS.
24 AND THEN, YOU KNOW, REALLY DO YOU WANT TO HAVE THE
25 RESPONSIBILITY OF A REPORT BACK TO THE PATIENT, OR

BARRISTERS' REPORTING SERVICE

1 ARE YOU CERTAIN THAT THAT INFORMATION SHOULD BE SORT
2 OF TRANSMITTED SCIENTIFICALLY FORWARD RATHER THAN
3 EVER GOING BACK TO THE PATIENT TO ALERT THEM TO SOME
4 SORT OF SUSCEPTIBILITY THAT THEY MAY HAVE AS A
5 RESULT OF THE RESEARCH.

6 SO I THINK THERE WAS A FAIRLY -- IT TURNED
7 UP IN MANY DIFFERENT OCCASIONS, AND THERE ARE ISSUES
8 TO SORT OF CONFIRM WE DID GO AHEAD AND FOLLOW THAT.
9 AND THAT WOULD BE UP TO, OF COURSE, US SEEING THE
10 COMPLETED DOCUMENT AND THEN HAVING A DISCUSSION WITH
11 THE ICOC IN DUE COURSE ABOUT WHAT WE SHOULD DO ABOUT
12 ANY RECOMMENDATIONS THAT ARE COMING FORWARD THERE.

13 DR. LOMAX: THANK YOU, ALAN. DID SOMEONE
14 JUST JOIN US?

15 MS. FEIT: THIS IS MARCY FEIT.

16 CHAIRMAN LO: MARCY, WELCOME.

17 DR. PRIETO: AND FRANCISCO PRIETO. I
18 JOINED A MINUTE OR TWO AGO.

19 CHAIRMAN LO: HI, FRANCISCO. WELCOME TO
20 BOTH.

21 DR. LOMAX: I WILL BE DOING ONE MORE ROUND
22 OF ROLL BEFORE WE DELIBERATE ON THE SPECIFIC ITEM.
23 I WAS JUST GIVING TIME FOR AS MANY PEOPLE TO GET ON
24 THE LINE AS POSSIBLE.

25 CHAIRMAN LO: SO, ALAN, IT SOUNDS LIKE WE

BARRISTERS' REPORTING SERVICE

1 THROUGH GEOFF WILL KEEP ABREAST OF THIS REPORT AND
2 LOOK IT OVER. AND CERTAINLY WE'LL BE AVAILABLE IF
3 THERE ARE ISSUES THAT NEED SWG -- STANDARDS WORKING
4 GROUP INPUT, OR WE CAN CERTAINLY HELP PROVIDE
5 REFERENCES. A LOT OF THESE ISSUES HAVE BEEN THOUGHT
6 THROUGH IN OTHER BIOBANK CONTEXTS FOR GENOMIC
7 RESEARCH.

8 DR. TROUNSON: RIGHT. ACTUALLY I ASKED
9 GEOFF LOMAX TO MAKE SURE THAT THERE WAS A CONNECTION
10 BETWEEN THIS RECENT WORKSHOP AND THE ONE THAT
11 OCCURRED BEFORE WHERE WE DID DISCUSS A LOT OF THE
12 ETHICAL AND LEGAL ISSUES AROUND BIOBANKING GENERALLY
13 AND THE POSSIBILITY OF AN IPS CELL BANK. SO,
14 INDEED, WE WANT TO CONNECT THAT, AND WE ALSO WANT TO
15 DRAW ON COMMENT FROM PEOPLE WHO WOULD HAVE SOME OF
16 THAT INTEREST OR EXPERTISE IN THIS SUBCOMMITTEE.
17 AND, OF COURSE, THE BOARD WOULD HAVE VIEWS ON THESE
18 MATTERS AND THE REPORT AS WELL.

19 CHAIRMAN LO: GREAT. OKAY. GEOFF, DO YOU
20 HAVE ANY OTHER UPDATES FOR THE WORKING GROUP?

21 DR. LOMAX: JUST QUICKLY, THE OTHER THING
22 WE'RE PLEASED TO REPORT ON IS THAT THE UNIVERSITY OF
23 CALIFORNIA LOS ANGELES HAS ADDED -- THEY'VE TAKEN
24 ADVANTAGE OF OUR HUMAN EMBRYONIC STEM CELL LINE
25 REGISTRATION PROGRAM, AND OUR REGISTRY HAS GROWN

BARRISTERS' REPORTING SERVICE

1 WITH AN ADDITION OF THREE OF THE UCLA LINES. AND
2 WANTED TO ADD THAT BECAUSE WE FEEL THAT THE REGISTRY
3 IS HELPING MAKE SURE THAT CIRM-DERIVED LINES ARE
4 GETTING OUT INTO THE BROADER COMMUNITY WITH ALL
5 KINDS OF GOOD PROVENANCE DOCUMENTATION THAT PEOPLE
6 ARE LOOKING FOR. AND UCLA HAS ALSO BEEN ELIGIBLE TO
7 GET INTO THE NIH REGISTRY BY GOING THROUGH THAT
8 PROCESS AS WELL.

9 CHAIRMAN LO: GREAT.

10 DR. LOMAX: SO AT THIS POINT I'D LIKE
11 TO -- IF IT'S OKAY WITH YOU, BERNIE, JUST TO GO
12 THROUGH THE ROLL ONCE MORE AND THEN MOVE TO THE
13 TOPIC AT HAND WHILE WE HAVE PEOPLE ON THE LINE. I
14 KNOW SOME PEOPLE HAVE TO LEAVE FAIRLY SOON.

15 CHAIRMAN LO: ABSOLUTELY. LET'S SORT OF
16 MOVE THROUGH THE AGENDA.

17 DR. LOMAX: MARCY FEIT.

18 MS. FEIT: YES.

19 DR. LOMAX: FRANCISCO PRIETO.

20 DR. PRIETO: HERE.

21 DR. LOMAX: JEFF SHEEHY.

22 MR. SHEEHY: HERE.

23 DR. LOMAX: BERNARD LO.

24 CHAIRMAN LO: HERE.

25 DR. LOMAX: TED PETERS.

BARRISTERS' REPORTING SERVICE

1 DR. PETERS: HERE.
2 DR. LOMAX: PATRICK TAYLOR.
3 DR. TAYLOR: YEP.
4 DR. LOMAX: TIMOTHY KAMP.
5 DR. KAMP: HERE.
6 DR. LOMAX: AND ROBERT TAYLOR.
7 DR. TAYLOR: HERE.
8 DR. LOMAX: DID I MISS ANYONE? OKAY. HOW
9 WOULD YOU LIKE TO PROCEED, BERNIE?
10 CHAIRMAN LO: WHY DON'T YOU SET THE ISSUES
11 UP FOR US.
12 DR. LOMAX: OKAY.
13 CHAIRMAN LO: GEOFF HAS ALWAYS WORKED VERY
14 HARD ON THIS AND SORT OF PROVIDED BACKGROUND
15 MATERIALS.
16 DR. LOMAX: OKAY. SO WHY DON'T I -- I'LL
17 BRIEFLY SUMMARIZE THE NOVEMBER 2D BRIEFING MEMO
18 WHICH WAS POSTED PUBLICLY. AND IN THAT MEMO YOU
19 WILL SEE A LIST -- WE HAVE A NUMBER OF JURISDICTIONS
20 THAT WE KNOW HAVE AN ACTIVE PROCESS EITHER FOR
21 LICENSING OR VERIFYING BOTH THE DERIVATION AND SORT
22 OF THE PROVENANCE, IF YOU WILL, OF HUMAN EMBRYONIC
23 STEM CELL LINES. AND WHAT WE'VE DONE HISTORICALLY
24 IS INCLUDED JURISDICTIONS WHERE WE FEEL THAT THEIR
25 STANDARDS ARE EQUAL OR SUFFICIENT TO THE LEVEL OF

BARRISTERS' REPORTING SERVICE

1 OVERSIGHT AND REVIEW THAT CIRM WOULD IMPOSE.

2 AND THE VALUE OF IDENTIFYING A

3 JURISDICTION IS IT MEANS THAT OUR GRANTEES MAY USE

4 STEM CELL LINES THAT ARE EITHER IN THOSE REGISTRIES

5 OR HAVE BEEN DERIVED UNDER THOSE LINES. AND THEY

6 CAN USE THEM IMMEDIATELY WITHOUT HAVING TO GO

7 THROUGH A PROCESS OF REVIEW BY THE INSTITUTIONAL

8 OVERSIGHT COMMITTEE. THAT REVIEW PROCESS TYPICALLY

9 TAKES TIME. THE COMMITTEE HAS TO COLLECT CONSENT

10 FORMS. IT HAS TO DO QUITE A BIT OF WORK IN ADVANCE

11 OF APPROVING THE USE OF THAT STEM CELL LINE.

12 AND, AGAIN, WHAT WE'VE TRIED TO DO IS

13 IDENTIFY LEGAL AND REGULATORY SYSTEMS WHERE WE KNOW

14 THAT WORK'S BEEN DONE PROPERLY UP FRONT. AND SO WE

15 DON'T NEED TO HAVE THAT WORK REPLICATED AT THE

16 INSTITUTIONAL LEVEL.

17 AGAIN, YOU HAVE A LIST OF SIX

18 JURISDICTIONS WE'VE APPROVED PREVIOUSLY, AND TODAY

19 WE WOULD LIKE YOU TO CONSIDER -- GET YOUR SENSE AS

20 TO WHETHER THE ICOC SHOULD INCLUDE THE AUSTRALIAN

21 MEDICAL RESEARCH COUNCIL LICENSING SCHEME AS AN

22 APPROVED JURISDICTIONAL POLICY.

23 DR. TROUNSON: SO JUST PERHAPS A LITTLE

24 TINY BIT MORE BACKGROUND ON THAT. THE AUSTRALIANS

25 WENT THROUGH TWO ROUNDS OF FEDERAL GOVERNMENT

BARRISTERS' REPORTING SERVICE

1 CONSIDERATION FOR LICENSING. AND THEY PRODUCED A
2 VERY DETAILED PROPOSAL WHICH REALLY MORE THAN
3 COVERS, I THINK, ANY OTHER JURISDICTION I'VE EVER
4 SEEN. IT'S VERY DEMANDING IN TERMS OF THE DONATION
5 MATERIAL AND THE CONSENT THAT'S REQUIRED, BUT ALSO
6 THE NEED TO STUDY THESE CELLS FOR MANY PATHOGENS,
7 POTENTIAL PATHOGENS, AND HISTORY OF ANY POSSIBLE
8 PATHOGEN IN THIS CASE OR PATHOLOGIES.

9 AND THESE CELL LINES THAT I THINK GEOFF IS
10 REFERRING TO, THERE ARE SIX OF THEM, I THINK, GEOFF.
11 ONE OF PARTICULAR INTEREST IS THAT THESE HAVE BEEN
12 MADE BY GMP AND THEY'RE COMPLETELY GMP COMPLIANT.
13 SO THEY WOULD BE UNUSUAL IN THE WORLD THAT THEY'RE
14 DERIVED -- NOT DERIVED. SO, YES, THE EMBRYONIC STEM
15 CELLS WAS DERIVED IN A GMP FACILITY, AND IT HAS ALL
16 OF THAT INFORMATION AND QUALITY ASSURANCE ATTACHED
17 TO THEM. SO THEY COULD BE OF USE TO RESEARCHERS IN
18 CALIFORNIA THROUGH THE COMPANY BIOTIME. AND WE'VE
19 HAD ELONA BAUM TALK TO BIOTIME AND WORK OUT AN
20 ACCESS METHOD FOR SCIENTISTS WHO ARE INTERESTED IN
21 THOSE PARTICULAR CELL LINES.

22 SO I THINK THEY ARE VERY RELEVANT TO OUR
23 TRANSLATIONAL AND EARLY CLINICAL WORK, AND THEY
24 COULD BE PARTICULARLY USEFUL FOR US IN SOME OR MANY
25 OF THE STUDIES THAT ARE GOING FORWARD THAT WANT TO

BARRISTERS' REPORTING SERVICE

1 USE EMBRYONIC STEM CELL-DERIVED CELLS PROVIDING
2 YOU FEEL THAT THE MATERIALS REQUIRED BY THE
3 AUSTRALIANS WELL AND TRULY FIT WITH WHAT YOU EXPECT
4 THE STANDARDS TO BE FOR CELL LINES THAT WE USE IN
5 CALIFORNIA.

6 CHAIRMAN LO: SO, GEOFF, CAN YOU ACTUALLY
7 WALK US THROUGH NOW IN DETAIL HOW THE AUSTRALIAN
8 OVERSIGHT AND REGULATION COMPARE TO OUR MES CIRM
9 GUIDELINES?

10 DR. LOMAX: YEAH. LET ME DO MY BEST
11 THERE. I HOPE THAT THE DETAIL IS SUFFICIENT, BUT
12 I'M GOING TO BE PARAPHRASING QUITE A BIT BECAUSE, AS
13 ALAN INDICATED, THE ACTUAL DOCUMENT WE WENT THROUGH
14 WAS A VERY EXTENSIVE SET OF REQUIREMENTS. BUT
15 WHAT'S REQUIRED IS ANY CENTER THAT'S PROPOSING TO
16 OBTAIN EMBRYOS FOR THE DERIVATION OF HUMAN EMBRYONIC
17 STEM CELL LINES MUST ACTUALLY APPLY FOR A LICENSE.
18 AND THIS IS ANALOGOUS TO WHAT WE APPROVED ON THE UK
19 HFEA. IT'S SORT OF THE CLOSEST COMPARATOR IN TERMS
20 OF HOW IT WORKS.

21 AND WHAT HAPPENS THERE IS THAT IN ORDER TO
22 GET THE LICENSE, THE FACILITY PROPOSING TO OBTAIN
23 THE EMBRYOS MUST BE ABLE TO DEMONSTRATE A CERTAIN
24 STANDARD OF CARE, A CERTAIN STANDARD OF PRACTICE.
25 SO THAT'S SORT OF LICENSING AT THE FACILITY LEVEL.

BARRISTERS' REPORTING SERVICE

1 AND THEN IT GOES ON TO WHERE IF YOU'RE
2 PROPOSING A PARTICULAR DERIVATION, SO, FOR INSTANCE,
3 THE EXAMPLE THAT ALAN RAISED WHERE THEY WERE
4 PROPOSING TO DEVELOP A SET OF LINES UNDER CLINICALLY
5 COMPLIANT CONDITIONS OR GMP COMPLIANT CONDITIONS, A
6 LICENSE NEED TO BE -- WOULD BE OBTAINED FOR THE
7 ACTUAL PROPOSED DERIVATION PROJECT. AND THAT WOULD
8 BE SOMEWHAT ANALOGOUS TO APPLYING TO AN IRB TO GET A
9 PROTOCOL APPROVED FOR A MORE NARROW PROJECT. SO YOU
10 HAVE A FACILITY THAT MUST BE LICENSED, THEN YOU HAVE
11 LICENSING AT THE PROJECT LEVEL.

12 AND THEN IN TERMS OF THE ACTUAL PROCESS OF
13 DERIVATION, THEY DO SOMETHING -- I THINK ALAN
14 SUGGESTED THIS WAS ONE OF THE MOST RIGOROUS, AND I
15 THINK IT'S VERY INTERESTING WHAT THEY DO. THEY
16 FIRST DO A CONSENT FOR OBTAINING THE EMBRYOS FOR
17 RESEARCH. SO THERE'S A FIRST LEVEL OF CONSENT WHICH
18 IS TO ATTEMPT TO DO THE DERIVATION. AND THEN IF THE
19 DERIVATION IS THEN SUCCESSFUL, THERE IS A RECONSENT
20 FOR THE USE OF THE DERIVED MATERIALS IN RESEARCH.
21 SO IT'S SORT OF A DOUBLE-BARRELED CONSENT, IF YOU
22 WILL.

23 SO THAT'S SORT OF A ROUGH OUTLINE OF THE
24 PROCESS AND THE SORT OF RELEVANT STEPS IN TERMS OF
25 SORT OF ETHICAL PROVENANCE. AND THEN IN YOUR

BARRISTERS' REPORTING SERVICE

1 BRIEFING MEMO THERE'S A TABLE THERE. AND UNLESS YOU
2 WANT ME TO, I'VE TRIED TO SORT OF DO A COMPARATOR IN
3 TERMS OF SOME OF THE SPECIFIC CONSENT ITEMS AND HOW
4 THEY COMPARE. MY VIEW IS THEY'RE SUBSTANTIALLY
5 SIMILAR, BUT OBVIOUSLY THE EXACT WORDS MAY DIFFER.
6 AND AGAIN, I THINK THERE WAS A LOT OF EMPHASIS IN
7 THE MATERIALS THAT I REVIEWED ON THE CONSENT PROCESS
8 AND THE FACT THERE ARE A NUMBER OF EDUCATIONAL
9 MATERIALS AND DOCUMENTS THAT AREN'T PART OF THE
10 FORMAL CONSENT FORM PROVIDED TO PROSPECTIVE COUPLES
11 AND DONORS THAT SORT OF OUTLINE SORT OF RESEARCH,
12 THE TYPE OF RESEARCH THAT TYPICALLY GOES ON WITH
13 STEM CELLS, ETC., ETC.

14 CHAIRMAN LO: SO I THINK WHAT'S IMPORTANT
15 FOR US IS THAT IF WE LOOK AT THE CIRM REGULATIONS, I
16 ALWAYS HAVE TROUBLE WITH THE SECTION, BUT 10080,
17 ACCEPTABLE RESEARCH MATERIALS. AND THEN UNDER 2,
18 THERE ARE A, B, C, FOUR CRITERIA FOR ACCEPTABLE STEM
19 CELL LINES. ONE IS THAT THERE WAS VOLUNTARY
20 INFORMED CONSENT AND INFORMED CONSENT FROM DONORS
21 IN THE CASE OF EMBRYOS. THE DONORS OF HUMAN GAMETES
22 OR EMBRYOS DID NOT RECEIVE VALUABLE CONSIDERATION.

23 DR. LOMAX: THAT'S RIGHT. MIGHT I JUST
24 ADD ONE POINT THERE, BERNIE. ALSO IT'S CONSENT FROM
25 ANY DONOR. AND ALSO IF IT'S A PARTNER SITUATION AND

BARRISTERS' REPORTING SERVICE

1 IT'S A NONGENETIC DONOR, THERE STILL NEEDS TO BE
2 APPROVAL BY THE PARTNER IN THE RELATIONSHIP. SO
3 AGAIN, THEY'RE VERY THOROUGH IN TERMS OF WHO'S
4 CONSENTING.

5 CHAIRMAN LO: RIGHT. AND SO NOW VALUABLE
6 CONSIDERATION FOR THE DONORS, BUT THEY ARE ALLOWED
7 TO BE REIMBURSED FOR OUT-OF-POCKET EXPENSES. GEOFF,
8 JUST TO SORT OF CONFIRM, SO THAT'S ALSO COVERED, MY
9 UNDERSTANDING, IN THE AUSTRALIA FRAMEWORK.

10 DR. LOMAX: CORRECT.

11 CHAIRMAN LO: AND THEN THE THIRD, C IS
12 DONATION OVERSEEN BY AN IRB OR EQUIVALENT. THIS IS
13 ACTUALLY UNDER THE LICENSING, THE FEDERAL -- THE
14 NATIONAL AUSTRALIAN LICENSING AGENCY. AND THEN THE
15 INDIVIDUALS WHO CONSENTED TO DONATING MATERIAL WERE
16 NOT REIMBURSED FOR THE DEPOSIT IN STORAGE PRIOR TO
17 DONATION.

18 DR. LOMAX: CORRECT.

19 CHAIRMAN LO: SO YOUR READING, GEOFF, IS
20 THAT THE AUSTRALIAN GUIDELINES AND OVERSIGHT SYSTEM
21 NEEDS TO BE -- ACTUALLY IN SOME CASES, IN SOME
22 INSTANCES THAT WAS WHAT WE DO IN THIS COUNTRY.

23 DR. LOMAX: THAT'S MY SENSE, CORRECT.

24 CHAIRMAN LO: ANY COMMENTS, QUESTIONS FROM
25 THE COMMITTEE?

BARRISTERS' REPORTING SERVICE

1 DR. PETERS: NOT FOR ME, THANKS.

2 CHAIRMAN LO: OKAY.

3 DR. TAYLOR: BERNIE, I GUESS I HAVE -- TO
4 ME IT REALLY DOES, IT LOOKS LIKE THE NHMRC
5 REQUIREMENTS ARE FRANKLY MORE STRINGENT THAN OUR
6 OWN. I WAS JUST CURIOUS ABOUT THE KIND OF PAYMENTS
7 OR INDUCEMENTS FOR DONATIONS SUBJECT TO THE
8 GUIDELINES OF THE NHMRC. HOW DOES THAT COMPARE TO
9 OUR GUIDELINES, OUR PERMISSIBLE EXPENSES?

10 CHAIRMAN LO: GEOFF.

11 DR. LOMAX: AGAIN, THE PERMISSIBLE
12 EXPENSES, THIS IS -- IT'S THE SAME AS OURS IN TERMS
13 OF NO PAYMENTS TO THE EMBRYO DONORS FOR STORAGE OR
14 FOR PROVIDING EMBRYOS. AND THEN ARE YOU REFERRING,
15 ROB, TO PERMISSIBLE EXPENSES FOR OOCYTE DONORS
16 BECAUSE THAT'S A SLIGHTLY DIFFERENT TOPIC, WHICH WE
17 CAN COVER, IF YOU LIKE, BUT IT'S A DIFFERENT TOPIC.

18 DR. TAYLOR: IT JUST SEEMS TO ME THAT IF
19 WE'RE GOING TO KIND OF GRANDFATHER THESE IN, THAT
20 THAT'S THE ONLY ISSUE THAT I WOULD THINK WOULD BE
21 RELEVANT OF THE LISTED ONES THAT ARE HERE.

22 DR. LOMAX: AND, AGAIN, FOR HUMAN
23 EMBRYONIC STEM CELL LINES, THERE REALLY ARE --
24 THERE'S NO PAYMENTS FOR ALL THE THINGS WE DON'T
25 ALLOW PAYMENTS FOR. THEY DO COVER PERMISSIBLE

BARRISTERS' REPORTING SERVICE

1 EXPENSES; BUT, AGAIN, MY READING IS IT'S THE SAME
2 SET OF CONSIDERATIONS. IT'S OUT-OF-POCKET EXPENSES,
3 BUT NOT PAYMENTS FOR NONCOST TO THE DONOR, IF YOU
4 WILL. I DON'T THINK I STATED THAT VERY
5 ARTICULATELY.

6 DR. TAYLOR: NO, THAT WAS REALLY BECAUSE,
7 YOU KNOW, I THINK OUR -- IT SEEMS THAT OUR
8 PERMISSIBLE EXPENSES OVER THE YEARS THAT I'VE BEEN
9 ON THIS COMMITTEE HAVE SOFTENED A LITTLE BIT. SO IF
10 THESE ARE KIND OF COMPATIBLE WITH THAT, THAT'S
11 GREAT.

12 DR. TROUNSON: JUST TO CLARIFY, I THINK
13 THE LAW IN AUSTRALIA SAYS THAT YOU CANNOT -- YOU
14 CANNOT COMPENSATE THE PATIENTS IN ANY WAY FOR THE
15 DONATION OF THE MATERIAL, NOR CAN YOU AS A RECIPIENT
16 OF EMBRYOS COMPENSATE THE DONORS. SO THERE IS
17 EFFECTIVELY NO COMPENSATION PAID BY THE DONORS AT
18 ALL OR PAID BY ANY OF THE INSTITUTIONS THAT ARE
19 MAKING THE CELLS.

20 DR. TAYLOR: I THINK THAT'S GREAT. I
21 WOULD JUST ASSUME THAT IS ONE OF THE POTENTIAL
22 TARGETS OF SOMEBODY WHO THINKS THIS ISN'T SUCH A
23 GOOD IDEA, BUT THE GMP ASPECT OF THIS IS A GREAT
24 PLUS. SO I THINK THIS IS A GREAT PLAN.

25 CHAIRMAN LO: ANY OTHER QUESTIONS,

BARRISTERS' REPORTING SERVICE

1 COMMENTS?

2 DR. LOMAX: DID ANYONE ELSE JOIN THE CALL?
3 OKAY. AND THEN I KNOW WE DID HAVE, I BELIEVE, A
4 PUBLIC COMMENT; IS THAT CORRECT? I'LL ASK SCOTT
5 TOCHER TO COVER THAT ITEM. DID ANYONE ELSE JUST
6 JOIN THE CALL?

7 DR. PETERS: THIS IS TED. I JUST GOT CUT
8 OFF AGAIN, SO REDIALED.

9 CHAIRMAN LO: SORRY YOU'RE HAVING TROUBLE.

10 MR. TOCHER: SO THIS IS A MESSAGE
11 SUBMITTED BY DON REED, AND HE STATES, "I REGRET MY
12 INABILITY TO ATTEND TODAY'S IMPORTANT MEETING, BUT I
13 WANTED TO AT LEAST LEND VERBAL SUPPORT TO THE
14 CONSIDERATION OF THE AUSTRALIAN STEM CELL LINES.

15 "ALWAYS ASSUMING THEY RISE TO CIRM'S HIGH
16 STANDARDS, THIS INTERNATIONAL COOPERATION IS A
17 PERFECT EXAMPLE OF THE WORLDWIDE EFFORT THAT IS
18 NEEDED TO DEFEAT THE GIANT PROBLEMS OF CHRONIC
19 DISEASE AND DISABILITY. WE HAVE ALREADY BENEFITED
20 FROM ONE AUSTRALIAN CHAMPION WHO HAS MIGRATED TO OUR
21 SHORE. IT SEEMS TO ME THAT WE SHOULD PROFIT FROM
22 THAT EXAMPLE ONCE MORE. THANK YOU. DON REED."

23 CHAIRMAN LO: OKAY.

24 DR. PETERS: THAT'S HELPFUL.

25 CHAIRMAN LO: OKAY. ANY OTHER COMMENTS,

BARRISTERS' REPORTING SERVICE

1 QUESTIONS FROM THE MEMBERS OF THE WORKING GROUP?

2 DR. PETERS: -- WHITE TO MIGRATE TO OUR
3 SHORES TOO. I BET YOU, ALAN, YOU KNOW HIM, HUH?

4 DR. LOMAX: DID YOU WANT TO SHARE SHERRY'S
5 VIEW AT THIS TIME, BERNIE? I KNOW YOU ALL HAD A
6 CHANCE TO TALK.

7 CHAIRMAN LO: YES. SHERRY SUPPORTED THE
8 ADOPTION OF -- SUPPORTED ADDING THE AUSTRALIAN LINES
9 APPROVED BY THE AUSTRALIAN LICENSING SYSTEM TO THE
10 LIST OF OTHER COUNTRIES' LINES THAT WE HAVE
11 AUTOMATICALLY ACCEPTED, THE UK, CANADA, JAPAN, FOR
12 EXAMPLE. AND HER ONLY CAVEAT WAS PROVIDED THERE
13 WERE NO CONCERNS RAISED BY MEMBERS OF THE COMMITTEE
14 DURING THIS CALL. AND AGAIN, SHE WAS SORRY SHE
15 COULDN'T PARTICIPATE WITH US.

16 SO IF THERE ARE NO CONCERNS OR FURTHER
17 QUESTIONS, DOES SOMEONE WANT TO MOVE THAT WE ADD
18 LINES APPROVED BY THE AUSTRALIAN NATIONAL LICENSING
19 AGENCY?

20 DR. PETERS: SO MOVED.

21 DR. LOMAX: WE DON'T ACTUALLY NEED TO MAKE
22 A MOTION BECAUSE, AGAIN, WE DON'T HAVE A QUORUM. I
23 THINK WHAT WE CAN TAKE AWAY FROM THIS, IF I'M NOT
24 MISTAKEN, SCOTT, THAT IT'S THE SENSE OF THE
25 COMMITTEE THAT THEY'RE IN SUPPORT OF THE MOTION, BUT

BARRISTERS' REPORTING SERVICE

1 WE ARE UNABLE TO FORMALLY MAKE A MOTION TO THE ICOC.

2 MR. TOCHER: THAT'S CORRECT.

3 CHAIRMAN LO: OKAY.

4 DR. KIESSLING: THIS IS ANN KIESSLING.

5 I'VE JOINED THE CALL. DOES THAT HELP THE QUORUM?

6 DR. LOMAX: WE'RE STILL SHORT.

7 CHAIRMAN LO: STILL SHORT. WELCOME, ANN.

8 BUT --

9 DR. PRIETO: THIS IS FRANCISCO PRIETO.

10 QUESTION. DOES THIS THEN GO TO THE ICOC FOR
11 DISPOSITION WITH A RECOMMENDATION FROM THE MEMBERS
12 OF THE COMMITTEE PRESENT?

13 CHAIRMAN LO: IT'S NOT SO MUCH A
14 RECOMMENDATION AS THAT IT THE SENSE OF THE PEOPLE ON
15 THE SWG PARTICIPATING ON THE CALL THAT FAVORABLE
16 ACCESS BE TAKEN TO ADD THESE AUSTRALIAN LINES TO THE
17 LIST OF LINES THAT WOULD AUTOMATICALLY BE APPROVED.

18 DR. PRIETO: OKAY. BUT THE ICOC WILL HAVE
19 TO ACT?

20 CHAIRMAN LO: RIGHT. IT WILL BE UP TO THE
21 ICOC. SO THOSE OF YOU ON THE ICOC, SO IT'S YOU,
22 MARCY, AND JEFF ON THIS CALL, WE'LL CALL ON YOU TO
23 CONVEY OUR SENTIMENTS TO THE ICOC AT THEIR MEETING.

24 DR. PRIETO: WHICH WILL BE IN A LITTLE
25 OVER A WEEK.

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1 CHAIRMAN LO: YES. YES. SO THIS WAS A
2 VERY TIMELY CALL. AS ALAN POINTED OUT, THE
3 POTENTIAL SCIENTIFIC BENEFIT FOR HAVING LINES THAT
4 MEET GMP STANDARDS COULD BE QUITE SUBSTANTIAL. SO
5 IT'S NICE TO BE ABLE TO MOVE ON THIS QUICKLY.

6 OKAY. ANY OTHER NEW BUSINESS? OKAY.

7 DR. LOMAX: WE'LL BE GETTING BACK TO YOU
8 ON A NUMBER OF ISSUES, LIKE WE SAID, BUT AT THIS
9 MOMENT WE'RE TRYING TO GEAR UP FOR THE ICOC MEETING
10 AND HAPPY HOLIDAYS.

11 CHAIRMAN LO: YES. I THINK THE MAIN THING
12 IS TO WISH EVERYONE HAPPY HOLIDAYS AND SAFE TRAVELS.
13 AND THANK YOU AGAIN FOR PARTICIPATING ON THE CALL,
14 AND WE'LL BE IN TOUCH WITH YOU AS THE NEED ARISES
15 NEXT YEAR. THANKS AGAIN.

16 (THE MEETING WAS THEN CONCLUDED AT
17 2:05 P.M.)

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BARRISTERS' REPORTING SERVICE

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 STANDARDS WORKING GROUP OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON MONDAY, NOVEMBER 22, 2010, 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