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

REGULAR MEETING

LOCATION: CIRM
210 KING STREET
SAN FRANCISCO, CALIFORNIA

DATE: NOVEMBER 13, 2006
10 A.M.

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

BRS FILE NO.: 76804

I N D E X

MONDAY, NOVEMBER 13, 2006

10:04 A.M.

DR. LOMAX: THE UPDATE IS REALLY FOCUSED ON GETTING EVERYONE UP TO SPEED ON THE DETAILS OF THE REGULATIONS. WHAT I'D LIKE TO DO IS DEFER THAT UPDATE UNTIL AFTER ED'S HAD A CHANCE TO GIVE YOU AN UPDATE ON THE WORK OF THE IP TASK FORCE BECAUSE MY UPDATE WILL SORT OF DOVETAIL RIGHT INTO OUR DISCUSSION OF THE REGULATIONS.

AS YOU ALL MAY RECALL, ONE OF THE THINGS THAT WE'VE BEEN DOING THROUGHOUT THE COURSE OF THESE MEETINGS IS TO STAY ABREAST OF THE WORK OF THE INTELLECTUAL PROPERTY TASK FORCE. YOU REMEMBER WE HAD A FORMAL PRESENTATION EARLIER IN THE YEAR ABOUT THEIR POLICY FOR NON-PROFITS. THEY'VE NOW BEEN WORKING DILIGENTLY ON A POLICY FOR FOR-PROFIT ORGANIZATIONS. SO ONE OF THE THINGS WE WANT TO DO THIS MORNING IS TO HAVE YOU ALL BE UPDATED ON SOME OF THEIR MOST RECENT WORK.

THERE WAS A SET OF SLIDES I SENT AROUND EARLY THIS MORNING HOPEFULLY YOU ALL HAVE. WE'LL BE USING THOSE SLIDES AS REFERENCE FOR THE UPDATE TODAY. SO WITH THAT, I'LL TURN IT OVER TO ED.

DR. PENHOET: THANK YOU. GOOD MORNING. AS

YOU JUST HEARD, WE HAVE BEEN WORKING ON THE POLICY FOR PROFIT-MAKING ORGANIZATIONS. AND IT'S A COMPANION PIECE TO THE POLICY THAT WE'VE ALREADY DEVELOPED FOR THE NON-PROFIT GRANTEES. THE STATUS OF THE NON-PROFIT POLICY IS IT WAS SUBMITTED TO THE ICOC BOARD NOW ABOUT SIX MONTHS AGO. WE'VE GONE THROUGH TWO ROUNDS OF THE OAL PROCESS. WE HAVE ONE REMAINING ITEM THAT WE'RE STILL WORKING ON, WHICH IS HOW TO ACTUALLY COME UP WITH A WORKABLE SOLUTION TO THE PROBLEM OF MAKING SURE THAT CALIFORNIANS DON'T PAY ANY MORE FOR THERAPIES THAT RESULT FROM OUR WORK THAN THE LOWEST PRICE AVAILABLE ELSEWHERE IN THE UNITED STATES.

IT'S A THORNY PROBLEM BECAUSE MANY OF THE GOVERNMENT PURCHASERS HAVE WHAT ARE CALLED MOST FAVORED NATION CLAUSES IN THEIR PURCHASING AGREEMENTS. IF YOU DON'T DO THIS CAREFULLY, YOU RUN A RISK THAT YOU'LL TRIP A DESTRUCTIVE SORT OF TRASHING OF PRICES IN THE WORST CASE TO ZERO AS THEY TUMBLE DOWN THIS MOST FAVORED NATION CLAUSE SYSTEM. SO WE'RE STILL WORKING. SCOTT TOCHER AND A NUMBER OF OTHERS ARE STILL WORKING TO FIND A FORMULA WHICH WILL GUARANTEE US LOWEST AVAILABLE PRICE, BUT WON'T RUN AFOUL OF NUMEROUS FEDERAL PROGRAMS AND OTHERS THAT ARE INVOLVED WITH PURCHASING.

BUT WITH THAT ONE EXCEPTION, I THINK THE

FOR-PROFIT POLICY IS MOVING ALONG, AND IT SHOULD BECOME -- WELL, WE'RE IN THE FINAL THROES OF THAT. THE NOT-FOR-PROFIT POLICY IS NOW IN THE FINAL THROES OF THE OAL PROCESS AND SHOULD BECOME STATE REGULATION VERY SOON. SO THAT'S GONE. WHILE IT'S BEEN A LOT OF WORK, AS YOU CAN IMAGINE, AS YOUR WORK HAS BEEN, BUT I THINK WE'RE QUITE PLEASED THAT WE'RE ALMOST AT THE END OF THAT SITUATION.

WE THEN TURNED OUR ATTENTION TO A POLICY TO PUT IN PLACE WHEN WE MAKE GRANTS TO COMPANIES BASICALLY. AND THAT'S OCCUPIED OUR TIME FOR THE LAST, WELL, ALMOST A YEAR NOW. SO GEOFF DID SEND AROUND SOME SLIDES. THERE ARE NOT MANY. SO IF YOU HAVE THEM AND YOU CAN OPEN THOSE SLIDES, I'LL GO QUICKLY THROUGH THE SLIDES.

THE FIRST ONE SIMPLY INDICATES WHAT WE HAVE DONE. WE HAD SIX PUBLIC MEETINGS DEVOTED TO THE SUBJECT. WE'VE HAD 18 DIFFERENT PRESENTATIONS. THE SIX PUBLIC MEETINGS WERE OF OUR TASK FORCE, AND THE 18 PRESENTATIONS ARE PRESENTATIONS THAT WERE GIVEN BY VARIOUS REPRESENTATIVES FROM INDUSTRY, FROM VARIOUS DIFFERENT INTERESTED GROUPS, ETC.

MARY AND I, ESPECIALLY MARY, HAVE DONE A SURVEY OF BEST PRACTICES OF ABOUT 20 ODD SOME FUNDING AGENCIES WHICH ARE NOW FUNDING COMPANIES. THE

RELATIVELY NEW PHENOMENON ACTUALLY IN THE FOUNDATION WORLD, HISTORICALLY MOST FUNDED ONLY UNIVERSITIES OR OTHER NON-PROFITS, BUT IN RECENT YEARS, QUITE A FEW OF THE DISEASE-ORIENTED FOUNDATIONS, THE JUVENILE DIABETES RESEARCH FOUNDATION, THE CYSTIC FIBROSIS FOUNDATION, THE WELLCOME TRUST IN THE UK, HAVE BECOME INVOLVED IN ACTUALLY FUNDING COMPANIES.

AND SO WE HAD -- THERE IS SOME EXPERIENCE OUT THERE ON THIS ISSUE, AND WE HAVE TALKED TO A NUMBER OF THOSE. SO WE'VE CONDUCTED INTERVIEWS WITH THEM, WE'VE READ THE LITERATURE, SO WE'VE DONE A FAIR AMOUNT OF HOMEWORK.

THE NEXT SLIDE, THE FEATURES OF THE PROPOSED POLICY ARE, FIRST OF ALL, THAT IT'S SIMILAR OVERALL TO THE NON-PROFIT POLICY. WELL, I GUESS THE NEXT SLIDE YOU HAVE IS A LITTLE CHART WHICH SHOWS ESSENTIALLY THE TWO POLICIES LINED UP ONE NEXT TO THE OTHER. IT SAYS FOR-PROFIT ON THE LEFT AND NON-PROFIT ON THE RIGHT, AS YOU CAN SEE.

AND BASICALLY CIRM FUNDING FOR THE NON-PROFIT SECTOR WILL GO PRIMARILY TO FUND BASIC SCIENCE, WHICH WILL LEAD TO AN INVENTION, WHICH, WHEN LICENSED TO A THIRD PARTY, WILL YIELD REVENUES TO THE NON-PROFIT ORGANIZATION. AND WE HAVE AGREED AFTER LOTS OF BACK AND FORTHS THAT 25 PERCENT OF WHATEVER THE NON-PROFIT

GRANTEE REVENUES ARE AFTER THE INVENTOR'S SHARE IS PAID AND A $500,000 THRESHOLD IS EXCEEDED WILL BE RETURNED TO THE STATE. SO THAT'S THE REMUNERATION FROM LICENSED TECHNOLOGY.

THERE ARE TWO OTHER COMPONENTS IN ADDITION TO THAT THAT ARE NON-PROFIT GRANTEES WILL AGREE TO, FIRST OF ALL, THAT ANY LICENSE THAT THEY GIVE TO CIRM-FUNDED TECHNOLOGY WILL HAVE A PLAN FOR ACCESS, WHICH IS DUE FROM THE EXCLUSIVE LICENSEE AT THE TIME OF COMMERCIALIZATION TO MAKE SURE THAT THE PRODUCTS OF THESE THINGS ARE AVAILABLE TO ESSENTIALLY UNINSURED AND OTHER PEOPLE WHO CAN'T AFFORD THESE THINGS NOT COVERED BY A GOVERNMENT PROGRAM.

SO THE PLAN FOR ACCESS, ORIGINALLY WE HAD AND, MAYBE WHEN WE TALKED TO YOU THE FIRST TIME, WE HAD PLANS FOR ACCESS DUE AT THE TIME OF LICENSE. THE INDUSTRY PEOPLE ARGUED THAT IT'S VERY HARD TO HAVE A PLAN -- WHEN THEY LICENSE TECHNOLOGY, IT'S USUALLY VERY EARLY ON AND COMMERCIALIZATION IS LIKELY TO BE SOME NUMBER OF YEARS DOWN THE ROAD, SO IT MADE MORE SENSE TO MOVE THAT UP TO THE TIME OF COMMERCIALIZATION.

AND THEN THE SECOND THING --

DR. PETERS: SO MAY I ASK THEN, THE PLAN FOR ACCESS REALLY SHOULD BE LATERAL TO THE PRODUCT DEVELOPMENT BOX THERE OR --

DR. PENHOET: WELL, IN THIS CASE THE LICENSE IS THE THIRD PARTY, NOT THE FOR-PROFIT COMPANY. SO IT SHOULD BE IN ONE SENSE, BUT THESE ARE THIRD-PARTY AGREEMENTS THAT WE'RE NOT GOING TO FUND DIRECTLY.

DR. PETERS: I SEE. OKAY.

DR. PENHOET: IF YOU ASSUME, FOR EXAMPLE, SOMEBODY AT BERKELEY INVENTS SOMETHING IMPORTANT, THEY LICENSE IT TO A PHARMACEUTICAL COMPANY, MERCK. TYPICALLY THE PHARMACEUTICAL COMPANY DOES ALL THESE THINGS AFTER THAT, AND WE MIGHT NOT BE INVOLVED IN FUNDING. BUT THEY STILL HAVE TO AGREE. WHETHER OR NOT WE FUND ANY MORE, THEY HAVE TO AGREE FOR THIS ACCESS PLAN AND FOR THE DISCOUNTED PRICING.

MS. CHARO: TWO OTHER QUICK QUESTIONS SINCE YOU SEEM TO BE WILLING TO CLARIFY FOR US. FIRST, WHEN YOU SAY THE 25 PERCENT OF THE GRANTEE REVENUES, BLAH, BLAH, BLAH ARE RETURNED TO THE STATE, IS THAT RETURNED TO GENERAL REVENUE, OR IS IT DEDICATED TO PAYING OFF THE BOND ISSUE?

AND SECOND, ALL OF THESE PROVISIONS SEEM TO APPLY ONLY TO THOSE WITH EXCLUSIVE LICENSES. ARE THERE ANY PROVISIONS THAT ARE BEING AIMED AT THOSE WHO GET NONEXCLUSIVE LICENSES?

DR. PENHOET: WELL, WE HAVE IN OUR POLICY AN ADMONITION THAT THEY SHOULD SEEK NONEXCLUSIVE LICENSING

WHENEVER POSSIBLE. AND THE VIEW IS THAT IF THERE ARE NONEXCLUSIVE LICENSEES, THAT THE MARKETPLACE ESSENTIALLY WILL SEE COMPETITION; AND, THEREFORE, THERE WILL BE LESS CONCERN ABOUT PRICING. WE'RE MOST CONCERNED WHEN THERE'S A MONOPOLY, THAT WE ACTUALLY HAVE SOME TEETH IN A PRICING PROVISION. SO THE ACCESS PLANS AND THE LOWER PRICES ARE FOR EXCLUSIVE LICENSEES, ASSUMING THAT IN THE CASE OF NONEXCLUSIVE LICENSES THE COMMERCIAL MARKETPLACE WILL SOMEHOW TAKE CARE OF THESE ISSUES WHEN THEY'RE IN COMPETITION WITH EACH OTHER.

MS. CHARO: ON THE REVENUES, THE GENERAL VERSUS BOND PAYMENT?

DR. PENHOET: AT THE MOMENT WE'VE BEEN ADVISED THAT THE MONIES GO BACK TO THE GENERAL FUND. THESE ARE GENERAL OBLIGATION BONDS, WHICH ALSO HAVE TO BE REPAID FROM THE GENERAL FUND.

MS. CHARO: GOT IT.

DR. PENHOET: BOTH THE INPUT AND OUTPUT COME FROM THE SAME PLACE.

MS. CHARO: THANK YOU FOR THE CLARIFICATION.

DR. PENHOET: YES. THERE IS A PROVISION IN BAYH-DOLE WHICH SAYS THAT THE UNIVERSITY'S SHARE IS SUPPOSED TO BE SPENT ON RESEARCH OR EDUCATION. AND WE WANT TO BE IN COMPLIANCE WITH BAYH-DOLE, AS MANY PEOPLE HAVE URGED US TO DO. AND SO WHAT GOES BACK TO THE

GENERAL FUND SHOULD BE EARMARKED FOR SCIENCE OR FOR RESEARCH OR FOR EDUCATION. THAT'S EASY TO DO BECAUSE A BIG FRACTION OF THE GENERAL FUND IS EDUCATION, BUT WE DON'T WANT TO RUN AFOUL OF BAYH-DOLE OR THE FEDERAL DEFINITION CONTAINED WITHIN BAYH-DOLE ABOUT WHAT MONEY SHOULD BE SPENT FOR. UNIVERSITIES ARE NOT ALLOWED TO SPEND THESE REVENUES, THEIR OWN SHARE, ON ANYTHING BUT RESEARCH AND EDUCATION. CAN'T LOBBY OR OTHER BUSINESS.

IF YOU GO OVER TO THE FOR-PROFIT SIDE, BASICALLY WE CAN FUND IN THE COMPANIES IN CALIFORNIA A VARIETY OF DIFFERENT STEPS IN THE DEVELOPMENT OF A PRODUCT. SO WE THINK THAT COMPANIES WILL APPLY FOR GRANTS TO DO BASIC SCIENCE. IF THEY MAKE INVENTIONS, AS INDICATED HERE, AND THEY LICENSE THEM TO THIRD PARTIES, THEN BASICALLY EVERYTHING IS THE SAME AS ON THE RIGHT-HAND SIDE OF THE SLIDE; THAT IS, THE LICENSES WILL CONTAIN EXACTLY THE SAME TERMS AS THE LICENSES FROM NON-PROFITS. SO THERE'S NO DIFFERENCE. THE ONLY DIFFERENCE IS THE DIFFERENCE BETWEEN 17 PERCENT ON THE RIGHT AND 25 PERCENT ON THE LEFT. THAT'S BECAUSE THE 25 PERCENT IS AFTER THE INVENTOR'S SHARE IS DEDUCTED, AND INVENTOR'S SHARE IS GENERALLY ABOUT A THIRD OF THE REVENUES.

SO IN THE CASE ON THE LEFT, INVENTORS INSIDE COMPANIES DON'T GET PAID FOR THEIR INVENTIONS, BUT THEY

GET PAID BY THE COMPANY. SO TO MAKE THIS SYMMETRICAL, WE'VE DEDUCTED A THIRD OF 25 OR 8 PERCENT FROM THE REVENUES ON THE LEFT-HAND SIDE FROM THE COMPANIES LICENSING REVENUES THAT WILL BE REPAID TO THE STATE IN ORDER TO ESSENTIALLY COMPENSATE THE COMPANY FOR THE INVENTOR'S SHARE AS IT HAS DONE IN THE UNIVERSITIES.

DR. PETERS: WHY DID YOU FEEL IT WAS NECESSARY TO MAKE THAT SYMMETRICAL?

DR. PENHOET: WELL, WE HAD LOTS OF DISCUSSION FROM VARIOUS DIFFERENT PEOPLE. AND I THINK THERE WAS THE THOUGHT THAT BASICALLY WE'VE EXPRESSED A VIEW, MANY PEOPLE, THAT THE GRANTS FOR BASIC SCIENCE OUGHT TO BE DONE WITHOUT BIAS ONE DIRECTION OR ANOTHER; THAT IF PEOPLE ARE APPLYING FOR A BASIC SCIENCE GRANT, IT SHOULD BE JUDGED SOLELY ON ITS MERITS, NOT ON WHETHER ONE WOULD GET A GREATER RETURN THAN THE OTHER FOR THE STATE, ETC. AND IN THIS CASE THE UNIVERSITIES ARE PAYING THEIR INVENTORS. SO WE TRIED TO MAKE THEM SYMMETRICAL AND CLASSICAL SIMPLY TO PUT EVERYBODY ON AN EVEN PLAYING FIELD.

I THINK THE PHILOSOPHY BEHIND IT IS THAT THE BEST SCIENCE SHOULD BE FUNDED WHETHER IT'S IN A COMPANY OR IN A UNIVERSITY. THAT WAS THE THOUGHT.

NOW, THERE IS ANOTHER CASE, WHICH IS THE MIDDLE COLUMN. IF THE COMPANY DECIDES NOT TO LICENSE

THE INVENTION, BUT, IN FACT, TO SO-CALLED FORWARD INTEGRATE ITSELF, THAT IS, DO THE PRECLINICAL WORK, THE PRODUCT DEVELOPMENT, AND MARKET THE PRODUCT, THEN THERE IS A DIFFERENT SET OF RULES THAT COME INTO PLAY BECAUSE THERE'S NO THIRD-PARTY LICENSEE. AND IT'S HERE WHERE WE'VE COME UP WITH POLICIES WHICH ARE FUNDAMENTALLY DIFFERENT THAN FOR THE NON-PROFIT.

NON-PROFITS DON'T DO ANY OF THIS WORK. THEY DON'T DO PRECLINICAL DEVELOPMENT, PRODUCT DEVELOPMENT, ETC. AND SO WE HAVE ANTICIPATED HERE THAT CIRM WOULD FUND THESE THINGS. IN FACT, IN THE MEETINGS WE HAD WITH COMPANY REPRESENTATIVES, THEY SAID THAT THE PLACE WHERE THEY'RE LIKELY TO NEED THE GREATEST AMOUNT OF HELP WAS IN THE PRECLINICAL DEVELOPMENT AND EARLY PRODUCT DEVELOPMENT. IF THEY GET AS FAR AS STAGE III CLINICAL TRIALS, THEY THOUGHT THEY CAN PROBABLY GET THOSE FUNDS FROM PRIVATE SOURCES, BUT THEY'LL NEED MONEY FOR THESE OTHER ACTIVITIES.

SECOND OF ALL, THERE'S A VIEW THAT WE SHOULD TRY TO ENCOURAGE COMPANIES TO ACTUALLY FORWARD INTEGRATE IN CALIFORNIA BECAUSE THERE'S A HIGH PROBABILITY A LICENSE WILL BE TO A COMPANY WHICH IS OUTSIDE CALIFORNIA. SO IF WE JUST LICENSE TECHNOLOGY FOR MERCK, FOR EXAMPLE, WHICH IS IN NEW JERSEY, THEN ALL THE DOWNSTREAM ACTIVITIES WOULD OCCUR IN NEW

JERSEY, NOT IN CALIFORNIA. AND WE ONE OF THE EXPLICIT GOALS OF PROP 71 IS TO DEVELOP A ROBUST STEM CELL INDUSTRY IN CALIFORNIA.

SO TAKING THAT IN MIND, WE OBVIOUSLY HAVE TO HAVE A DIFFERENT SET OF CIRCUMSTANCES FOR THE COMPANIES THAN WE HAVE FOR THE NON-PROFITS BECAUSE THEY ARE DOING THIS DOWNSTREAM WORK AS INDICATED HERE.

AND IF YOU GO TO SLIDE 5, WE SEE THAT WHAT HAPPENS IS, STARTING AT THE TOP, IT SAYS FOR-PROFIT REVENUE SHARING. IT SAYS AT THE TOP IF COMMERCIALIZATION OCCURS, ALL FOR-PROFIT GRANTEES WILL RETURN THREE TIMES THE TOTAL GRANT AWARD AFTER REVENUES EXCEED A $500,000 THRESHOLD. THAT'S THE SAME AS WE HAVE IN THE LICENSED POLICY. SO THIS IS -- THERE WAS A LOT OF DISCUSSION, AS YOU CAN IMAGINE, AROUND THIS, WHAT THE PROPER AMOUNT WOULD BE.

THE COMPANIES DON'T MIND PAYING THE MONEY BACK, BUT THEY WANTED A CAP ON THE TOTAL AMOUNT OF THEIR EXPOSURE SO THEY DIDN'T HAVE SOME UNKNOWN AMOUNT. AFTER A LOT OF DISCUSSION, WE AGREED ON THIS 3 X NUMBER AFTER THE REVENUES EXCEED $500,000. HOWEVER, IF THESE BECOME SIGNIFICANT PRODUCTS, THAT IS, THEY ACHIEVE SO-CALLED BLOCKBUSTER STATUS -- WE DEFINED BLOCKBUSTER STATUS AS SALES OF $250 MILLION A YEAR OR MORE. IF YOU GO TO THE LEFT, IF WE'VE INVESTED LESS THAN $5 MILLION

IN THE PROJECT, WHEN IT REACHES $250 MILLION IN ANY SINGLE YEAR, THEY'LL PAY ANOTHER THREE TIMES THAT. SO AT THAT POINT WE WOULD HAVE GOTTEN SIXFOLD RETURN ON THE INVESTMENT THAT WE MADE IN THE PROJECT. AND IF THEY REACH $500 MILLION A YEAR, THEY WOULD PAY ANOTHER 3 X, OR WE WOULD GET NINEFOLD RETURN ON THE INVESTMENT THAT WE MADE IN THAT PROJECT.

DR. PETERS: IS THAT A ONE-TIME ONLY, OR WOULD THAT BE FOR EACH YEAR IN WHICH THOSE --

DR. PENHOET: THAT'S A ONE-TIME ONLY PAYMENT. IF YOU GO TO THE RIGHT, AND WE'VE INVESTED MORE THAN $5 MILLION IN A PROJECT, AND THERE ARE NO PATENTS INVOLVED, WE DIDN'T FUND ANY PATENTED WORK THAT ENDS UP IN A PATENT, GOES OVER TO THE SAME BOX ON THE LEFT. HOWEVER, IF THERE ARE CIRM-FUNDED PATENTS INVOLVED AND THE BLOCKBUSTER REACHES SALES OF MORE THAN $500 MILLION A YEAR, THEN 3 X AT 250, ANOTHER 3 X AT 500, AND THEN FOR THE LIFETIME OF THE PATENT, THEY WILL PAY A 1-PERCENT ROYALTY ON ALL THE SALES OVER $500 MILLION. SO THAT ADDRESSES YOUR QUESTION, TED. IF IT BECOMES A BIG PRODUCT, THEN THE STATE WILL GET A 1-PERCENT ROYALTY.

SO BASICALLY WITH RESPECT TO ALMOST EVERYTHING ELSE IN THE NON-PROFIT POLICY, WE HAVE GOOD SYMMETRY. WE STILL HAVE -- BY THE WAY, THESE

REQUIREMENTS OF THE RETURN NOW ARE BASED ON $1 IN. ANY INVESTMENT AT ALL IN ONE OF THESE COMPANIES, THEN THEY AGREE TO THIS PAYBACK PROVISION, BUT THEY ALSO AGREE TO THE ACCESS PROVISION AND THE PRICING PROVISION THAT WE WILL HAVE. SO IF THEY TAKE ANY MONEY FROM US WHATSOEVER, THEY'RE OBLIGATED TO BOTH ACCESS AND FOR DISCOUNTED PRICING.

IN ADDITION TO THAT, WE DID DECIDE AND WE STILL HAVEN'T FIGURED OUT EXACTLY HOW WE'RE GOING TO DO THIS, BUT I THINK IT'S AN IMPORTANT CONCEPT. IF YOU LOOK THROUGH EVERYTHING I'VE JUST TOLD YOU, CALIFORNIA CITIZENS ARE MODESTLY ADVANTAGED RELATIVE TO PEOPLE WHO LIVE IN IOWA OR SOME OTHER PLACE RELATIVE TO THIS, BUT DON'T HAVE A HUGE ADVANTAGE. SO WHEN WE TALKED ABOUT, WELL, WHAT MIGHT BE ANOTHER ADVANTAGE THAT CALIFORNIA CITIZENS COULD GET OUT OF THIS, WE CAME UP WITH THAT IF THERE WAS LIMITED THERAPEUTIC AVAILABILITY FOR ONE REASON OR ANOTHER, AN ORGANIZATION LACKS -- I WAS CEO OF CHIRON --

MS. CHARO: MAY I INTERRUPT FOR A MOMENT? THERE'S SOMEBODY WHOSE PHONE IS BRINGING IN AN AWFUL LOT OF BACKGROUND NOISE. IS THERE ANYBODY ON LINE WHO'S IN A NOISY ENVIRONMENT?

(INTERRUPTION IN PROCEEDINGS.)

DR. PENHOET: SO IN MY OWN EXPERIENCE, WE HAD

A DRUG APPROVED FOR TREATING MULTIPLE SCLEROSIS. WE DIDN'T HAVE ENOUGH CAPACITY TO MANUFACTURE ENOUGH FOR THE ENTIRE MARKET, SO WE HAD TO CONDUCT A LOTTERY BASICALLY. IT WAS A NIGHTMARE, TO BE HONEST WITH YOU, BUT IT WAS THE ONLY FAIR WAY TO DO IT. AND EVERYBODY WITH INFLUENCE THOUGHT THEY COULD CALL US AND SOMEHOW JUMP THE LINE IN THE LOTTERY. AND WE DIDN'T DO ANY OF THAT, AS YOU CAN IMAGINE. SO IT'S NOT THE ONLY TIME IT'S HAPPENED. AND COMPANIES GENERALLY DEAL WITH IT IN SOME WAY, SHAPE, OR FORM LIKE THAT.

BUT IN OUR MEETING LAST FRIDAY, DUANE ROTH BROUGHT UP THE POINT THAT IF THERE WAS A LIMITED THERAPEUTIC AVAILABILITY, AT LEAST CALIFORNIANS OUGHT TO GET SOME KIND OF PREFERENCE. COMPANY REPRESENTATIVES SAID IT WOULD BE VIRTUALLY IMPOSSIBLE FOR THEM TO GIVE ALL THE SUPPLY TO CALIFORNIANS, BUT THAT THEY CAN LIST CRITERIA, SEVERITY OF THE DISEASE, ETC., AND THAT THEY CAN PUT IN THE CRITERIA, THEY THOUGHT, SOME WEIGHTING FOR CALIFORNIA RESIDENTS, SO CALIFORNIA RESIDENTS WOULD HAVE SOME PREFERENTIAL ACCESS. WE HAVE YET TO COME UP WITH EXACTLY HOW THIS IS GOING TO WORK, SO I'M JUST BRINGING IT TO YOU TODAY AS A CONCEPT, BUT THAT WAS PART OF THE RECOMMENDATION OF OUR GROUP LAST WEEK.

AS I SAID BEFORE, IT'S A FIRST-DOLLAR

REQUIREMENT. IF COMPANIES TAKE ANY MONEY FROM CIRM, THEY HAVE TO AGREE TO ACCESS, THEY HAVE TO AGREE TO PRICING, AND THEY HAVE TO AGREE TO DO THEIR BEST TO GIVE PREFERENTIAL ACCESS TO CALIFORNIANS IN THE CASE OF LIMITED AVAILABILITY.

I MIGHT ADD ONE OF THE REASONS WE'RE HAVING TROUBLE ON THE PRICING FRONT IS ALL THE PRICING THINGS IN THE FEDERAL GOVERNMENT DEDICATE PRICES, THAT WE HAD EARLIER, ARE ALL ONLY FOR DRUGS. AND STEM CELL THERAPIES -- SOME DRUGS MAY EMERGE FROM OUR PROGRAMS, BUT STEM CELL THERAPIES ARE GOING TO BE MORE AKIN TO TRANSPLANTS PROBABLY. THEY ARE TRANSPLANTS. AND THERE IS A COMPLETELY DIFFERENT SET OF RULES FOR HOW TRANSPLANTS GET PAID FOR, MORE HETEROGENEOUS. SO THAT'S PART OF THE REASON THAT WE'RE STUCK ON PRICING IS TRYING TO FIND A WORKABLE SYSTEM THERE.

SO I THINK THAT REALLY IS THE BULK OF WHAT WE HAVE DECIDED. WE'RE GOING TO BRING THIS -- WE'D LOVE SOME COMMENTS FROM YOU NOW; BUT BARRING ANY FURTHER COMPLICATIONS, WE WILL REFINE THESE CONCEPTS AND BRING THEM TO THE ICOC BOARD AT ITS DECEMBER BOARD MEETING.

(INTERRUPTION IN PROCEEDINGS.)

DR. PENHOET: TED'S ASKED A COUPLE OF QUESTIONS.

CHAIRMAN LO: QUESTIONS FROM THE PHONE

PEOPLE?

DR. TAYLOR: I'VE GOT A QUESTION IF I COULD GET IT IN BEFORE THE NEXT INTERRUPTION. THIS IS KIND OF IN THE SPIRIT OF SORT OF SYMMETRY AND FAIRNESS. I MISSED THE LAST PART OF YOUR CONVERSATION, BUT I'M WONDERING A LITTLE BIT WHAT MIGHT HAVE HAPPENED TO KIND OF MIDDLE-CLASS CALIFORNIANS BECAUSE IT LOOKS TO ME LIKE THE DISCOUNTS ARE ONLY REALLY GOING TO HAPPEN FOR PATIENTS WHOSE THERAPIES ARE PURCHASED WITH PUBLIC FUNDS, ACCORDING TO WHAT'S WRITTEN HERE. AND IF THESE THINGS REALLY BECOME THERAPIES, THEY'RE GOING TO BE EXPENSIVE AS HELL. EVERYBODY IS GOING TO NEED A LOT OF ASSISTANCE TO GET ACCESS TO THESE.

MY QUESTION IS KIND OF WHAT HAPPENS TO THE PEOPLE WHO SORT OF SUPPORTED THE BOND ISSUE?

DR. PENHOET: WELL, IF THEY'RE UNINSURED, THEY FALL UNDER THE ACCESS PROGRAM.

DR. TAYLOR: THAT'S EASY.

DR. PENHOET: IF THEY'RE INSURED, THEN THE ONUS IS REALLY ON THE INSURERS IN THIS CASE, NOT ON THE COMPANIES. SO WE HAVEN'T REALLY IN -- AND NONE OF THESE HAVE WE REALLY DISCUSSED PREFERENTIAL PRICING ACROSS THE BOARD FOR CALIFORNIANS. THE PRIMARY NEGOTIATORS NOW ON PRICE ARE THE INSURERS AND THE STATE. SO WE TRIED TO ADDRESS THE UNINSURED, BUT WE

HAVEN'T REALLY THOUGHT ABOUT HAVING A PROGRAM FOR DISCOUNT PRICING ACROSS THE BOARD IN CALIFORNIA.

DR. LOMAX: ANY OTHER QUESTIONS?

DR. PENHOET: IF YOU GUYS HAVE ANY FURTHER THOUGHTS, AND YOU CAN GET THEM TO US BEFORE THE DECEMBER 8TH ICOC MEETING, IT WOULD BE VERY MUCH APPRECIATED.

DR. PETERS: THANKS FOR THIS REPORT. TOUGH STUFF THAT YOU HAVE TO DEAL WITH.

DR. PENHOET: MARY HAS POINTED OUT TO ME SHE SURVIVED IT. WE'VE PROBABLY BEEN IN MORE CROSSFIRE THAN ANY OTHER GROUP. THE POLAR EXTREMES OF WHAT WE FACED ARE VERY WIDE. I THINK MARY HAS DONE A WONDERFUL JOB OF STEERING US.

CHAIRMAN LO: I THINK WE'VE TRIED TO TAKE INTO ACCOUNT BOTH THE EQUITY ISSUES AND FEASIBILITY ISSUES FOR FOR-PROFIT COMPANIES.

DR. PENHOET: THANK YOU VERY MUCH.

CHAIRMAN LO: I'M GOING TO TURN THIS OVER TO GEOFF FOR AN UPDATE, A STAFF REPORT UPDATE.

DR. LOMAX: TO BRING FOLKS WHO MADE HAVE ENTERED THE CALL A LITTLE BIT LATE, WE'VE HEARD FROM THE IP TASK FORCE. WE HAD AN UPDATE ON THEIR WORK BECAUSE THAT'S SOMETHING THAT, AS I WILL GET TO IN THE UPDATE, DID AT ONE POINT RELATE OR STILL RELATES TO

SORT OF THE BROADER STANDARDS FOR CIRM.

I THINK AT THIS POINT WHAT I'LL DO IS A ROLL CALL BECAUSE WHOEVER IS GOING TO BE ON THE LINE AT THIS POINT SHOULD BE THERE. SO I'LL COMMENCE WITH THE ROLL CALL.

MARCY FEIT.

MS. FEIT: HERE.

DR. LOMAX: ROBERT KLEIN. SHERRY LANSING. FRANCISCO. JEFF SHEEHY. JONATHAN SHESTACK. ALTA CHARO.

MS. CHARO: HERE.

DR. LOMAX: BERNARD LO.

CHAIRMAN LO: HERE.

DR. LOMAX: PATRICIA KING. TED PETERS.

DR. PETERS: HERE.

DR. LOMAX: KEVIN EGGAN. ANN KIESSLING. JEFFREY KORDOWER. KENNETH OLDEN. JANET ROWLEY. ROD TAYLOR.

DR. TAYLOR: HERE.

DR. LOMAX: JOHN WAGNER.

DR. WAGNER: HERE.

DR. LOMAX: JAMES WILLERSON. OKAY.

IS EVERYTHING COMING ACROSS OKAY NOW, BETH?

THE REPORTER: PRETTY GOOD. THANKS.

DR. LOMAX: IF YOU RECALL, OUR LAST MEETING

WAS ON JULY 17TH. WE HELD A TELECONFERENCE TO DECIDE REGULATORY LANGUAGE FOR SECTION 100095 WHICH DEALT WITH THE ISSUE OF DONATION OF EGGS. IN THAT MEETING WE APPROVED LANGUAGE WHICH PROHIBITED EGG DONORS', PAID EGG DONORS' EGGS FROM BEING USED IN CIRM-FUNDED RESEARCH.

ON AUGUST 20TH BERNIE PRESENTED THE ENTIRE PACKAGE TO THE ICOC. THE PACKAGE INCLUDED THE REGULATION AND A SUMMARY OF OUR WORK. THAT PACKAGE WAS APPROVED BY THE ICOC. THE PACKAGE WAS THEN SUBMITTED TO THE OFFICE OF ADMINISTRATIVE LAW IN LATE AUGUST.

JUST SO YOU KNOW, THE OFFICE OF ADMINISTRATIVE LAW HAD AN ADDITIONAL 60 POINTS, QUESTIONS, CLARIFICATIONS FOR US, SO WITH HEROIC EFFORT BY SCOTT TOCHER, WE WERE ABLE TO MAKE SURE THAT ALL THOSE RESPONSES WERE ADEQUATE. AND WE GOT THEM TO OFFICE OF ADMINISTRATIVE LAW IN A TIMELY MANNER, AND THEY APPROVED THE REGULATIONS IN LATE OR THE MIDDLE OF OCTOBER. AND THEY WILL ACTUALLY TAKE EFFECT OFFICIALLY ON THE 22D OF NOVEMBER.

NOW, THERE WAS ONE ISSUE I WANT TO DRAW TO EVERYONE'S ATTENTION WITH REGARD TO TWO SECTIONS. THERE WERE TWO FINAL SECTIONS IN THE REGULATIONS WHICH ONE WAS SECTION 100120 WHICH DEALT WITH REPORTING, AND SECTION 100130 WHICH DEALT WITH COMPLIANCE WITH THE

CIRM IP REGULATIONS.

NOW, I'LL START WITH THE 130 SECTION BECAUSE THAT SECTION IS ESSENTIALLY REDUNDANT. IT SAYS THOU SHALT COMPLY WITH CALIFORNIA STATE LAW. WE'RE SIMPLY GOING TO DROP THAT SECTION. THERE'S NO REASON TO REPEAT A REQUIREMENT THAT'S GOING TO BE IN LAW ANYWAY UNDER THE INTELLECTUAL PROPERTY REQUIREMENTS. JUST TO REMIND FOLKS, THE GENESIS OF THAT REGULATION WAS WE ORIGINALLY WANTED LANGUAGE ABOUT SHARING INTELLECTUAL PROPERTY AND SHARING MATERIALS. WE DID THAT AT PERHAPS THE SECOND MEETING LAST YEAR. AND SUBSEQUENTLY THE IP TASK FORCE SORT OF TOOK OVER WITH THAT ENTIRE BODY OF WORK, WHICH, AS WE'VE HEARD AGAIN TODAY, IS NOW A VERY EXTENSIVE CONVERSATION AND VERY DETAILED CONVERSATION. WE APPRECIATE THE FACT THEY'VE TAKEN THAT UP. AGAIN, THERE WILL BE REGULATIONS COMING OUT THAT ADDRESS FAR MORE THAN WE EVER COULD HAVE IMAGINED WHEN WE FIRST THOUGHT OF THAT SECTION. BUT FOR THE PURPOSES OF OUR REGULATIONS, THAT LANGUAGE IS ENTIRELY REDUNDANT AND UNNECESSARY.

THE SECTION 100120, WHICH DEALS WITH REPORTING, WE ARE CURRENTLY DRAFTING SOME REVISED LANGUAGE TO ADDRESS CONCERNS THAT THE OFFICE OF ADMINISTRATIVE LAW RAISED. AND THE REASON WE WITHDREW THE SECTION IS BECAUSE THE OFFICE OF ADMINISTRATIVE LAW

POINTED OUT THERE WAS SOME LANGUAGE IN THAT SECTION, THAT THERE WAS NO WAY WE COULD SORT OF FIX IT WITHOUT CHANGING THE LANGUAGE IN A MANNER WHICH WILL REQUIRE US TO RE-POST IT, GET NEW PUBLIC COMMENT, AND GET ICOC APPROVAL. SO WE'RE NOW IN THE PROCESS OF DOING THAT, AND I WILL CIRCULATE THAT REVISED LANGUAGE TO THE WORKING GROUP TODAY. WE ARE IN THE PROCESS OF RE-POSTING IT. THAT WILL, AGAIN, GO UP FOR 15-DAY COMMENT, AND WE'LL ALSO LOOK FORWARD TO THE ICOC CONSIDERING THAT LANGUAGE AT THE DECEMBER 7TH MEETING.

SO WITH THAT SAID, MORE OR LESS THE ENTIRE BODY OF REGULATION WAS APPROVED, AND WE'RE EXTRAORDINARILY PLEASED WITH THAT WITH THE FEW HOUSEKEEPING ITEMS I JUST MENTIONED.

ARE THERE ANY QUESTIONS OR THOUGHTS THERE?

CHAIRMAN LO: IF I COULD JUST INTERRUPT FOR A MINUTE. FIRST, I WANT TO THANK SCOTT TOCHER AND GEOFF LOMAX FOR SORT OF THEIR HEROIC EFFORTS OF GETTING THIS THROUGH OAL. IT WAS A VERY DETAILED AND COMPLICATED BACK AND FORTH, BACK AND FORTH. AND I THINK, AS GEOFF SAID, THESE WILL NOW BE GOING INTO EFFECT.

AND BECAUSE WE WANTED TO HAVE THE BULK OF THE REGULATIONS GO INTO EFFECT AS SOON AS POSSIBLE, WE WANTED TO TAKE OUT THE 100200 SECTION AND DEAL WITH THAT SEPARATELY SO AS NOT TO SLOW UP ALL THE OTHER

PROVISIONS.

DR. LOMAX: ANY OTHER QUESTIONS THERE? THEN BEFORE WE BEGIN THE SUBSTANCE TODAY, THERE'S JUST ONE OTHER ITEM I WANT TO BRING TO YOUR ATTENTION. WE ARE TRYING TO SET A DATE IN APRIL. AND SO PLEASE PAY ATTENTION TO E-MAIL. WE'RE GOING TO BE CIRCULATING OR WE'VE BEEN CIRCULATING -- WE HAVEN'T CIRCULATED YET. YOU WILL BE GETTING SOME REQUESTS TO CONSIDER DATES IN APRIL OF NEXT YEAR. WHAT WE'D LIKE TO BE ABLE TO DO IS SET UP A MEETING WHICH WE WOULD BILL AS OUR SORT OF ANNUAL MEETING.

PROPOSITION 71 SPECIFIES THE WORKING GROUP SHOULD HAVE AN ANNUAL MEETING WHERE WE SEEK TO GET MAXIMUM ATTENDANCE. AND THE PLAN FOR THAT MEETING AT THE MOMENT, THE TENTATIVE PLAN, IS WE WOULD LIKE TO DO SOME EVALUATION AND SOME WORK WITH INSTITUTIONS WHO ARE IMPLEMENTING OUR REGULATIONS. AND WHAT WE HOPE TO DO IS IN ADVANCE OF THE MEETING HOLD SOME TYPE OF WORKSHOP WHERE WE WILL GATHER FEEDBACK AND LEARN ABOUT THEIR EXPERIENCE WITH THE REGULATIONS. AND THEN FOR THE ANNUAL MEETING, BRING SORT OF THE LESSONS LEARNED FROM THE FIRST PHASE OF IMPLEMENTATION BACK TO THE WORKING GROUP.

SO I THINK IT WILL BE A NICE BREAK FOR THE WORKING GROUP. RATHER THAN HAVING AN AGGRESSIVE AGENDA

OF MORE REGULATIONS TO THINK ABOUT, IT'S A CHANCE TO STEP BACK AND THINK ABOUT HOW THINGS HAVE BEEN WORKING OUT AND THINK ABOUT SETTING AN AGENDA FOR THE FUTURE BASED ON THE LESSONS LEARNED FROM WHAT WE'VE ALREADY PUT IN PLACE. SO, AGAIN, WE'LL BE GETTING BACK TO FOLKS WITH DATES, BUT WE WILL STRONGLY ENCOURAGE YOUR ATTENDANCE, AND I THINK IT WILL BE A VERY DIFFERENT MEETING FROM WHAT WE'VE BEEN USED TO FOR THE LAST YEAR AND A HALF WHERE OBVIOUSLY WE'VE BEEN PURSUING A VERY AGGRESSIVE TIMELINE.

MS. CHARO: GEOFF, IF I MAY, THIS IS ALTA. THERE MAY BE AN OPPORTUNITY FOR SOME COLLABORATIVE LEVERAGING WITH THE NATIONAL ACADEMIES ON EXACTLY THIS THING. THE NAS HAD A MEETING LAST WEEK -- IN FACT, BERNIE ATTENDED -- AT WHICH PEOPLE WHO ARE TRYING TO SET UP ESCRO'S WERE INVITED TO DO JUST THE KIND OF THING, GIVE FEEDBACK ON WHAT'S BEEN WORKING AND WHAT HASN'T.

ONE OF THE THINGS WE'RE LIKELY TO DO NEXT IS TO EXPAND THAT EXERCISE INTO A COLLECTION OF REGIONAL MEETINGS TO GET A BROADER SET OF RESPONSES FROM ESCRO PEOPLE. AND IT MAY BE THAT IF WE CAN COORDINATE THE NATIONAL ACADEMY AND THE CIRM INFORMATION SESSIONS, WE'LL BE ABLE TO GET SOME VERY DETAILED WORK, NOT ONLY ON THE REGS, BUT ON THE COMMITTEES AND HOW WELL THE

COMMITTEES ARE FUNCTIONING WITHIN THOSE REGS.

CHAIRMAN LO: I THINK THAT WOULD BE A GREAT IDEA. AS YOU KNOW, THERE'S A LOT OF INTEREST IN THE INSTITUTIONS FOR SORT OF FINDING OUT WHAT OTHER INSTITUTIONS ARE DOING AND TRYING TO FIGURE OUT HOW TO DO WHAT THEY'RE DOING BETTER IN TERMS OF OVERSIGHT. SO THIS COULD BE A VERY PRODUCTIVE MEETING. WE'LL TRY AND WORK ON THE SCHEDULE WITH YOU.

MS. CHARO: OKAY.

CHAIRMAN LO: MY UNDERSTANDING IS THIS IS GOING TO BE IN LOS ANGELES, THIS MEETING, OR IS THAT NOT CLEAR AT THIS POINT?

MS. CHARO: WE WERE THINKING -- THE CIRM MEETING?

CHAIRMAN LO: THE CIRM MEETING, I MISSPOKE, WILL BE IN SAN FRANCISCO. SO I DON'T KNOW IF, ALTA, THAT FEEDS IN WITH YOUR PLANS.

MS. CHARO: WE HAVEN'T SETTLED ON A PLACE. WE HAD INITIALLY BEEN THINKING SOUTHERN CALIFORNIA. BUT, ANYWAY, WE CAN FOLLOW THIS UP LATER OFFLINE WITH MORE DETAIL.

DR. LOMAX: WE'RE FLEXIBLE IN THAT REGARD. CERTAINLY SAN FRANCISCO HAS ADVANTAGES, BUT WE'RE FLEXIBLE.

MS. CHARO: OKAY.

DR. LOMAX: FINALLY, A REMINDER. ON APRIL 4TH THIS YEAR YOU ALL APPROVED LANGUAGE THAT WAS CONTAINED IN ATTACHMENT 1. AND FOR MEMBERS OF THE PUBLIC, THAT'S LANGUAGE -- LET ME JUST GET THE TITLE OF THE DOCUMENT. IT'S "CONSENSUS RECOMMENDATIONS FOR CIRM MES REGULATIONS," AND IT'S THE NEW SECTION 100085, USE OF FETAL TISSUE. YOU RECOMMENDED THIS LANGUAGE; THE ICOC APPROVED IT AS INTERIM REGULATION. AND BECAUSE IT EXISTS AS INTERIM REGULATION, WE SORT OF PROCEDURALLY NEED TO COME BACK TO THIS LANGUAGE AND DECIDE WHAT WE WANT TO HAVE IN PLACE FOR FINAL REGULATION. AN INTERIM REGULATION UNDER PROPOSITION 71 IS IN PLACE FOR 270 DAYS. THE CLOCK IS WINDING DOWN ON THAT 270 DAYS. SO WE NEED TO MAKE A RECOMMENDATION FOR THE ICOC FOR A FINAL RECOMMENDATION WITH REGARD TO LANGUAGE ON FETAL TISSUE.

I THINK AT THIS POINT I CAN TURN IT OVER TO YOU, BERNIE, AND WE'LL GO FROM THERE. I'LL HAVE BERNIE SORT OF LEAD THE POLICY DISCUSSION AT THIS POINT.

CHAIRMAN LO: THANKS, GEOFF. JUST TO SORT OF PUT US IN CONTEXT, WHAT WE'VE WANTED TO DO WITH THE FETAL TISSUE REGULATIONS, AND THERE IS RESEARCH BEING DONE WITH FETALLY DERIVED STEM CELLS, AND WE CAN ANTICIPATE THAT THERE WOULD BE A HIGH LIKELIHOOD OF THERE BEING SOME APPLICATIONS TO CIRM FOR FUNDING FOR

WORK IN SUCH LINES. AND THIS SECTION, WHEN WE WROTE IT, WHAT WE REALLY WANTED TO DO WAS MAKE SURE THAT WE WERE CONSISTENT WITH EXISTING FEDERAL REGULATION IN 45 CFR 46 AND ALSO FEDERAL LAW REGARDING TRANSPLANTATION.

WHAT WE DID NOT WANT TO DO WAS TO SORT OF OPEN THE CONTENTIOUS ISSUE OF CONSENT FROM PEOPLE OTHER THAN THE BIRTH MOTHER. AS YOU RECALL, WE HAD AN EXTENSIVE DISCUSSION OF THIS IS SUCH A COMPLICATED ISSUE, THAT UNLESS THERE WAS REALLY GOOD REASON TO DO SO, WE THOUGHT THAT WE SHOULD NOT TRY AND ADDRESS THAT WITH THESE IN THIS CONTEXT.

SO WHAT WE PROPOSED IN SECTIONS A, B, AND C ARE REALLY JUST A RESTATEMENT OF WHAT IS EXISTING FEDERAL REGULATION AND LAW. ALTHOUGH IT'S REDUNDANT, I THINK THE IDEA WAS TO BRING IT TOGETHER IN ONE PLACE SO THAT CIRM APPLICANTS AND CIRM GRANTEES WOULD REALLY KNOW WHAT THERE IS. AS YOU KNOW, ALTA AND STAFF DID A LOT OF DIGGING AROUND TO SORT OF FIND ALL APPLICABLE FEDERAL REGULATION AND LAW. WE THOUGHT IT WOULD BE USEFUL TO PUT IT IN ONE PLACE. WE ALSO REFERRED TO CALIFORNIA LAW JUST TO REMIND PEOPLE THEY NEED TO COMPLY WITH THAT.

I THINK THOSE FIRST THREE SECTIONS ARE JUST SORT OF RESTATING CURRENT FEDERAL POLICY, AND THEY HAVE

TO DO WITH NOT HAVING THE PROSPECT OF DONATION ALTER THE TIMING OR THE POSITION FOR ABORTION, THAT THERE BE NO RESTRICTIONS ON WHO MAY RECEIVE THE DONATED TISSUE. AND THE ATTENDING PHYSICIAN FOR THE WOMAN TERMINATING PREGNANCY SHOULD DISCLOSE ANY INTEREST IN RESEARCH. SO THESE ARE, AGAIN, HOPEFULLY STANDARD BUT IMPORTANT SAFEGUARDS.

I WANT TO SEPARATE OUT FOR DISCUSSION THE LAST SECTION D, WHICH REALLY HAS TO DO WITH GOOD TISSUE PRACTICE REQUIREMENT. AND THERE ARE TWO ISSUES I THINK WE NEED TO TAKE INTO ACCOUNT. FIRST, THE COMPLIANCE WITH GOOD TISSUE REQUIREMENTS REALLY EXTENDS BEYOND FETAL TISSUE TO ANY TISSUE THAT MIGHT BE USED FOR TRANSPLANTATION. SO ONE QUESTION WHICH WAS BROUGHT UP BY OUR LEGAL CONSULTANTS IS WHETHER THIS IS THE RIGHT PLACE -- THIS SECTION IS THE RIGHT PLACE AND WHETHER WE SHOULD TAKE THAT OUT AND THINK OF WHERE WE MIGHT WANT TO INTEGRATE IT AS WE DO MORE GENERALLY WITH ALL KINDS OF TRANSPLANTED TISSUE.

THE OTHER ISSUE IS, AGAIN, ALL WE'RE BASICALLY SAYING IS GOOD CURRENT TISSUE REQUIREMENTS AS PUBLISHED BY FDA AND THE FEDERAL REGISTER. AGAIN, WE SORT OF WALKED THE LINE BETWEEN REDUNDANCY AND DUPLICATION VERSUS SORT OF JUST BRINGING TO PEOPLE'S ATTENTION REGULATORY REQUIREMENTS THEY MAY NOT BE AWARE

OF. I THINK THE REASON FOR BRINGING THIS TO PEOPLE'S ATTENTION IS THERE MAY BE IMPLICATIONS FOR AT LEAST ESTABLISHING CONTACT WITH WHAT, I GUESS WE'D CALLED ORIGINALLY, THE MALE GENETIC PROGENITOR OR THE FEMALE GENETIC PROGENITOR, WHO MAY, OF COURSE, BE DIFFERENT THAN THE BIRTH MOTHER. THAT IF THERE IS AN FDA REQUIREMENT FOR SOME SORT OF SCREENING OF THE GENETIC DONORS, THEN AT THE TIME YOU'RE CONTEMPLATING DERIVING A FETAL TISSUE, YOU WOULD WANT TO PRESUMABLY THINK ABOUT WHETHER YOU'RE GOING TO BE ABLE TO COMPLY WITH THOSE REGULATIONS.

SO IT'S A MATTER OF RAISING THE ISSUE SO THAT, AT THE TIME OF DERIVATION, THE STEM CELL SCIENTIST KNOWS OF THE POSSIBLE NEED FOR SCREENING THE GENETIC PROGENITORS. LET ME STOP THERE AND SEE IF THERE'S COMMENT FROM THOSE ON THE CALL OR TED HERE IN THE OFFICE.

DR. PETERS: BERNIE, SO IT'S NOT REALLY A QUESTION AS TO WHETHER WE WANT D. IT'S A QUESTION OF WHERE IT OUGHT TO BE, WHETHER IT SHOULD BE ASSOCIATED WITH FETAL TISSUE, EVEN THOUGH IT DEALS WITH NONFETAL TISSUE. IS THAT THE QUESTION?

CHAIRMAN LO: RIGHT. THERE ARE TWO ISSUES. ONE IS THERE IS A POINT OF VIEW THAT SAYS, WELL, ALL WE'RE DOING IS SAYING DON'T FORGET TO COMPLY WITH THESE

FEDERAL REGULATIONS. SO THERE IS A POINT OF VIEW SAYING WHY BUILD IN TOO MUCH REDUNDANCY AND DUPLICATION? SO I THINK IT IS A SHOULD WE AT ALL. AND THEN YOU'RE RIGHT. THE NEXT QUESTION, ASSUMING WE DO WANT TO PUT THAT IN, I THINK IT'S MORE AS A KIND OF REMINDER TO JOG THE ATTENTION OF THE STEM CELL RESEARCHER, IS THIS IS THE RIGHT SECTION SINCE IT APPLIES MORE BROADLY?

ALTA, DO YOU HAVE THOUGHTS ON THIS? I KNOW YOU'VE THOUGHT A LOT ABOUT REGULATIONS AND THIS PARTICULAR SECTION AS WELL.

MS. CHARO: YEAH. I MUST CONFESS MY FIRST INSTINCT ALWAYS IS TO NOT RECITE THE LAW THAT HAS TO ALREADY BE FOLLOWED IF ONLY BECAUSE THERE'S ALWAYS THE RISK THAT ONE HAS UNINTENTIONALLY DONE SOMETHING IN THE DRAFTING THAT CREATES SOME KIND OF INCONSISTENCY.

PUTTING ASIDE THAT JUST INSTINCT, GOING TO THE QUESTION OF THE EDUCATION, I GUESS I'D ASK US TO THINK FOR A SECOND ABOUT WHO THE REAL AUDIENCE IS OF THE REGULATIONS AS OPPOSED TO ACCOMPANYING EDUCATIONAL MATERIAL THAT MAY IN THE FUTURE BE DEVELOPED FOR THE STEM CELL COMMUNITY MORE BROADLY OR FOR THE PUBLIC TO EXPLAIN THE BASIC THRUST OF THE REGS AND THINGS TO KEEP IN MIND.

I AGREE WITH YOU THAT UNIVERSITIES AND

COMPANIES THAT ARE TAKING CIRM FUNDS DO NEED TO BE AWARE AT THE OUTSET OF STEPS THEY NEED TO TAKE EARLY IN ORDER TO MAKE SURE THAT DOWNSTREAM THEY'RE NOT PRECLUDED FROM TAKING FURTHER THERAPEUTIC ACTIONS. I'M JUST NOT YET COMPLETELY SURE THAT THE REGULATIONS ARE THE BEST VEHICLE FOR ACHIEVING THAT EDUCATIONAL GOAL.

CHAIRMAN LO: OTHER THOUGHTS ON THAT?

DR. WAGNER: I AGREE WITH ALTA THAT I'M NOT SURE THAT THIS IS ACTUALLY GOING TO BE ACHIEVING THE GOAL THAT YOU'RE HOPING TO ACHIEVE. I UNDERSTAND THAT YOU WANT PEOPLE TO BE AWARE OF WHAT THE REGULATIONS ARE, BUT MANY OF THE PEOPLE WHO WILL BE USING SUCH TISSUE, IF IT'S NOT FOR SPECIFICALLY RESEARCH THAT MIGHT HAVE SOME THERAPEUTIC INTENT, WILL ALREADY KNOW THOSE REGULATIONS MOST LIKELY. ON THE OTHER HAND, YOU KNOW, IF THEY DON'T KNOW THEM, I'M NOT SURE THAT THIS IS GOING TO PROVIDE THEM WITH ADDITIONAL INFORMATION THAT THEY WOULD HAVE NOT BEEN LOOKING FOR TO BEGIN WITH.

I THINK THAT, IN PART, THE OTHER THING WE HAVE TO DO IS WE HAVE TO STEP BACK AND FIND OUT WHAT IS IT THAT THE FDA WILL REQUIRE. THESE REGULATIONS AREN'T THAT SPECIFIC IN CASES LIKE THIS. SO, FOR EXAMPLE, THE ONE COMMENT THAT YOU MADE, WHICH WAS RELATED TO THE GENETICS OF THE DONORS, FOR EXAMPLE, EVEN WITH CORD

BLOOD TODAY, WE DON'T HAVE ANY ACCESS NECESSARILY TO THE FATHER'S GENETIC HISTORY. SO THE FDA IS MONITORING IT, BUT DOESN'T REALLY KNOW HOW TO ENFORCE IT OR REGULATE IT AT THIS POINT IN TIME. SO THERE'S A LOT OF UNKNOWNS. I'M NOT SURE THAT STATING THIS OR PROVIDING THE DOCUMENTS HERE IS REALLY GOING TO BE TOO HELPFUL SINCE IT'S NOT CLEAR ANYWAY.

CHAIRMAN LO: HOW DO YOU FEEL ABOUT ALTA'S SUGGESTION THAT IT'S REALLY MORE OF AN EDUCATIONAL ISSUE THAN A REGULATORY ISSUE?

DR. WAGNER: I THINK IT IS AN EDUCATIONAL ISSUE IN GENERAL. I THINK THAT, IN PART, ALTHOUGH NOT RELATED SPECIFICALLY TO THE FETAL TISSUE, THIS IS ALSO ONE OF THE NEXT ITEMS THAT WE HOPE TO BRING UP AT THE NATIONAL ACADEMY IS TO REALLY FIGURE OUT WITH THE FDA WHAT IT IS THAT THEY'RE LOOKING FOR AND HOW WE MIGHT BE ABLE TO MAKE IT SO THAT IT IS MORE MEANINGFUL TO THE INVESTIGATORS THAT MIGHT BE DEVELOPING OR DERIVING NEW STEM CELL LINES OR EVEN INCLUDING FETAL TISSUE.

WE'RE TRYING TO PUSH THEM A LITTLE BY GIVING THEM SOME INFORMATION UP FRONT SAYING THIS IS HOW WE WOULD BEGIN TO THINK ABOUT HOW WE WOULD USE SUCH TISSUE. NOW COMMENT ON IT RATHER THAN JUST ASKING FOR, YOU KNOW, ADVICE UP FRONT WITHOUT ANY REAL STRUCTURE.

CHAIRMAN LO: ANY OTHER COMMENTS ON THIS FROM

OTHERS ON THE CALL?

DR. PRIETO: I JUST WANTED TO LET YOU KNOW THAT I HAD JOINED THE MEETING. AND I JUST WONDERED IF WE DO NOT INCLUDE SOMETHING LIKE THIS IN REGULATIONS, DO WE HAVE ANOTHER VEHICLE THAT WE WOULD USE THAT WOULD BE APPROPRIATE, OR IS THIS JUST SOMETHING BEST LEFT ALONE?

DR. LOMAX: ONE OF THE VEHICLES IS WITHIN THE GRANT ITSELF AND WITHIN THE POLICY. I MEAN THERE'S OTHER WAYS OF APPROACHING INSTITUTIONS PARTICULARLY IN THE BACK AND FORTH THAT WILL GO ON IN THE ADMINISTRATION OF THE GRANT.

DR. PRIETO: RIGHT. THROUGH GRANTS ADMINISTRATION. OKAY.

DR. LOMAX: CERTAINLY THE EVOLUTION -- NOT THE EVOLUTION, BUT INITIALLY THIS FETAL TISSUE POLICY WAS, YOU KNOW, IN NEED -- THE GRANTS GROUP SAW THE NEED FOR THIS POLICY, SO THEY ASKED US TO SORT OF FORMULATE AND BRING THE POLICY FORWARD. AGAIN, WE CAN COME BACK TO THEM AND SORT OF SAY, WELL, WITH THIS POLICY IN PLACE, HERE ARE SOME -- WE CAN BRING RECOMMENDATIONS OR WHATEVER WE FEEL IS USEFUL.

THE ONLY SORT OF CONSIDERATION IS THE POSSIBILITY OF WHAT THEY CALL SORT OF BACK-DOOR REGULATION, BUT I THINK IN THE CASE OF PROVIDING SOME

EDUCATIONAL GUIDANCE ON AN EXISTING FEDERAL REGULATION, SCOTT, CORRECT ME IF I'M WRONG, I THINK WE CERTAINLY HAVE THE ABILITY TO SORT OF QUERY AND PROVIDE BASIC FACTUAL INFORMATION ABOUT EXISTING LAW. YOU SEE ANY PROBLEM THERE?

MR. TOCHER: NO. IN CONCEPT, NO. I THINK PROBABLY HAVING IT IN THE GAP WOULD BE, I PRESUME, SOMETHING ALONG THE LINES, GIVEN THE NATURE OF WHAT THE GAP IS, THAT DOCUMENT, THAT IT WOULD BE ALONG THE LINES OF A REPORTING REQUIREMENT, NOT AN ACTUAL SUBSTANTIVE REQUIREMENT, BUT JUST IN THE LIST OF REPORTS AND INFORMATION THAT CIRM WOULD BE ENTITLED TO GET FROM THE GRANTEE WOULD BE AN ASSURANCE, FOR INSTANCE, OF COMPLIANCE WITH, AND THIS WOULD BE AN EXAMPLE, OF THESE FEDERAL REGULATIONS. IF IT WERE IN A GAP SITUATION, THAT'S PROBABLY WHAT IT WOULD LOOK LIKE.

CHAIRMAN LO: I THINK THERE'S ONE OTHER MECHANISM, AND THAT'S PERHAPS THROUGH THE TRAINING GRANTS, THAT THERE ARE PLANS TO HAVE AN ANNUAL MEETING OF THE GRANTEES. AND TO THE EXTENT THAT THAT WOULD BE AN EDUCATIONAL PROGRAM, IT'S CERTAINLY NOT OUTSIDE THE QUESTION. IT WOULD DEPEND ON THOSE ORGANIZING THAT MEETING TO HAVE SOMETHING ON THAT SORT OF BREAKING ETHICAL ISSUES. AND THIS MIGHT BE SOMETHING ON THAT LIST. SO I THINK THERE ARE WAYS OF HAVING AN

EDUCATIONAL IMPACT THROUGH THE VARIOUS ACTIVITIES CIRM DOES.

MR. TOCHER: RIGHT. AND SO LONG AS THE TEST TO HAVING IT IN THE REGULATION OR HAVING IT IN THE FORM YOU DESCRIBED IS JUST WHAT THE CIRM ENDS UP DOING WITH THE INFORMATION. IF WE END UP HINGING A GRANT ON THIS SORT OF THING, MAKING A CONSEQUENCE OF IT, THEN THAT'S WHERE YOU GET INTO THE FIELD OF WANTING TO MAKE SURE IT'S NOT AN UNDERGROUND REGULATION, BUT THAT IT'S VERY EXPLICIT.

CHAIRMAN LO: SO WE'VE HEARD A NUMBER OF COMMENTS SAYING, I THINK, IF I UNDERSTAND IT RIGHT, THE GIST WOULD BE TO REALLY REMOVE D FROM THESE REGULATIONS AND SORT OF TRANSFER THE THOUGHT INTO SOME SORT OF EDUCATIONAL SORT OF INFORMAL MANDATE, BUT NOT TO PUT IT IN REGULATIONS. DOES THAT FAIRLY SUMMARIZE WHAT I HEARD ON THE CONVERSATION FROM, GOING BACKWARDS, JOHN, ALTA, AND TED, I THINK? OTHER THOUGHTS ON THIS?

DR. WAGNER: THIS IS JOHN AGAIN. ONE THING, IN THE COVER LETTER WE SAY REGULATIONS GOVERNING THE USE OF FETAL TISSUE. IN THE BOTTOM YOU HAVE RECOMMENDATION. THEN YOU ALSO MAKE A STATEMENT OF CORD BLOOD. HOWEVER, THE PIECE OF PAPER THAT SAYS AGENDA ITEM NO. 16, DOES IT SAY ANYWHERE IN THERE CORD BLOOD BECAUSE I DON'T THINK OF CORD BLOOD AS FETAL TISSUE?

CHAIRMAN LO: THESE SHOULD BE FETAL TISSUE REGULATIONS.

DR. LOMAX: THAT MAY BE A RELIC. AT ONE POINT A LONG TIME AGO, WE WERE DEALING WITH BOTH THESE ISSUES TOGETHER, AND THEN THEY SEPARATED OUT BECAUSE WE DEALT WITH CORD BLOOD IN A DIFFERENT PART OF THE REGULATION. SO THAT MAY JUST BE A RELIC WHERE THERE'S A MISHEADER THERE.

THESE REGULATIONS ARE INTENDED -- ARE WRITTEN TO DEAL EXCLUSIVELY WITH FETAL TISSUE.

DR. WAGNER: OKAY. JUST WANTED TO MAKE SURE.

CHAIRMAN LO: WE DO NOT HAVE A QUORUM, BUT I THINK IT'S THE SENSE OF THE MEETING THAT WE FORWARD ON TO THE ICOC SECTION A, B, AND C OF THE 100085 AND DELETE SECTION D FROM WHAT WE WOULD ASK THE ICOC TO APPROVE. I GUESS FIRST I'D LIKE TO JUST ASK IF THERE'S ANY PUBLIC COMMENT? THERE ARE A NUMBER OF PEOPLE HERE. I DON'T KNOW IF THERE ARE PUBLIC PEOPLE ON THE CALL. ANYONE FROM THE PUBLIC LIKE TO MAKE A COMMENT ON THIS ISSUE OF FETAL TISSUE REGULATIONS? OKAY. THERE IS NONE.

WOULD SOMEONE LIKE TO MOVE THAT WE RECOMMEND THE SENSE OF THE COMMITTEE, NOT A BINDING RESOLUTION, THAT WE SUGGEST THAT THE ICOC ADOPT A, B, AND C OF SECTION 100085?

DR. PETERS: SO MOVED.

CHAIRMAN LO: SOMEONE WANT TO SECOND THAT?

MS. CHARO: SECOND.

CHAIRMAN LO: THANKS, ALTA. WHY DON'T WE JUST GO THROUGH AND VOTE HERE. TED YOU WANT TO VOTE.

DR. PETERS: AYE.

CHAIRMAN LO: I'LL VOTE AYE. ALTA?

MS. CHARO: AYE.

CHAIRMAN LO: JOHN?

DR. WAGNER: AYE.

CHAIRMAN LO: FRANCISCO?

DR. PRIETO: AYE.

CHAIRMAN LO: IS ROB STILL ON THE CALL? I THINK HE GOT ON HIS PLANE. ANYBODY ELSE DID I MISS?

DR. LOMAX: MARCY, ARE YOU STILL ON THE CALL?

MS. FEIT: AYE.

CHAIRMAN LO: OKAY. ANYONE ELSE I MISSED FROM THE SWG? OKAY. GOOD. SO, AGAIN, THIS IS ONLY A SENSE OF THE COMMITTEE, BUT I THINK THIS WILL BE VERY USEFUL FOR THE ICOC. AND THE PLAN IS TO PRESENT THIS TO THE ICOC FOR THEIR APPROVAL DECEMBER 7TH AND ALSO TO POST THIS FOR A 15-DAY PUBLIC COMMENT PERIOD. SO THIS WILL SORT OF MOVE ALONG AS AN ADDITIONAL REGULATION TO BE ADDED TO WHAT'S ALREADY BEEN APPROVED.

DR. LOMAX: ONE THING I'LL ADD ON THAT FDA

LANGUAGE, IN THE SECTION I DESCRIBED EARLIER ABOUT REPORTING, ONE OF THE THINGS OAL POINTED OUT TO US IS WE HAD SOME LANGUAGE, AND I'M SORRY I DON'T HAVE THE EXACT TEXT IN FRONT OF ME, BUT WE SAID SOMETHING TO THE REGARD THAT GRANTEES SHALL MAINTAIN RECORDS OF ANY SORT OF SAFETY SCREENING OF MATERIALS. AND OAL SORT OF FLAGGED THAT AS VERY AMBIGUOUS. SO IN THE REDRAFT OF THE REGULATION THAT, AGAIN, I'LL CIRCULATE LATER TODAY, WE ACTUALLY INDICATED THAT THEY SHOULD KEEP RECORDS OF ANY SCREENING REQUIRED AS A RESULT OF THE FDA REGULATIONS.

SO WE DO ACTUALLY HAVE ONE SMALL FLAG IN THE REGULATIONS THAT SAYS IF YOU'RE DOING SAFETY SCREENING PURSUANT TO THESE FDA REQUIREMENTS, WHICH RELATE SPECIFICALLY TO TISSUE AND MATERIALS INTENDED FOR HUMAN TRANSPLANTATION, THEN YOU NEED TO KEEP RECORDS OF THAT AND THAT THOSE RECORDS NEED TO BE AVAILABLE AT CIRM'S REQUEST. SO WE DO, IN FACT, HAVE A SMALL FLAG IN THE REGULATIONS UNDER THAT SPECIFIC SET OF CIRCUMSTANCES WHERE INSTITUTIONS HAVE DEVELOPED MATERIALS INTENDED FOR TRANSPLANTATION. IT'S JUST IN A RECORDKEEPING SECTION AS OPPOSED TO FETAL TISSUE SECTION.

CHAIRMAN LO: THIS IS IN SECTION 100200, WHICH WILL BE CIRCULATED TODAY.

DR. LOMAX: CIRCULATED TODAY, CORRECT.

MS. CHARO: IF I MAY. JUST A SUGGESTION FOR SOMETHING TO THINK ABOUT ONCE CIRM IS UP AND RUNNING WITH FULL FUNDING. BUT A NUMBER OF UNIVERSITIES ARE STRUGGLING WITH WAYS TO WALK THEIR INVESTIGATORS THROUGH THE APPLICABLE RULES AND TO SIMULTANEOUSLY EDUCATE THEM AND ALSO ENSURE COMPLIANCE. AND SEVERAL ARE TRYING TO DEVELOP WEB-BASED INTERFACES THAT WILL ASK YOU A SERIES OF QUESTIONS AND THEN AUTOMATICALLY DIRECT YOU TO THE NEXT APPROPRIATE AREA THE WAY TURBOTAX DOES IS WALK YOU THROUGH A TAX RETURN.

IT DOES STRIKE ME THAT OUR REGULATIONS ARE SO COMPLEX AND INTERRELATE WITH THINGS LIKE THE FDA RULES AND MANY OTHERS, THAT SOMETHING THAT WOULD HELP THE RESEARCH COMMUNITY AND THE UNIVERSITIES WOULD BE SOME DEGREE OF STANDARDIZATION HERE. AND IT MIGHT BE POSSIBLE TO HELP THE GRANTS TO DEVELOP SUCH AN INTERFACE THAT ONLY NEEDS MINIMAL TWEAKING FOR EACH INSTITUTION, WHICH WILL HAVE SLIGHTLY DIFFERENT COMMITTEES PERHAPS IN NAMES AND THINGS, BUT BASICALLY TO WALK THEM THROUGH.

CHAIRMAN LO: OKAY. SUGGESTION FOR A NEW CIRM ACTIVITY. AND LET'S --

DR. LOMAX: I THINK WE CAN THINK ABOUT THAT. THERE'S CERTAINLY, IF YOU LOOK AT THE STRATEGIC PLAN, I THINK THERE'S CATEGORICAL SORT OF POTS OF MONEY THAT

PERHAPS COULD BE USED TOWARD SORT OF COMPLIANCE AND QUALITY ASSURANCE. SO I THINK THERE'S CERTAINLY SPACE IN THE STRATEGIC PLAN TO SORT OF LOOK AT THOSE TYPES OF ISSUES.

MS. CHARO: OKAY.

DR. LOMAX: I'LL ADD THAT TO MY SORT OF RUNNING LIST OF GOOD IDEAS.

CHAIRMAN LO: BUT YOU'RE RIGHT. COMPUTERS CAN REMIND PEOPLE OF THINGS THAT ARE HARD FOR THE HUMAN BRAIN TO KEEP IN ALL AT ONE TIME. OTHER COMMENTS, THOUGHTS, SUGGESTIONS?

DR. WAGNER: BASED ON WHAT GEOFF HAD PREVIOUSLY DISCUSSED ABOUT KEEPING SOME RECORD OF WHAT TESTS HAVE BEEN PERFORMED, YOU KNOW, SINCE IT HAS TO BE DONE, IT FILLS A NUMBER OF WHAT YOU'RE LOOKING TO DO, WHY NOT JUST ASK FOR A COPY OF THE IND? YOU CAN'T USE FETAL TISSUE WITHOUT AN IND. THIS PROVIDES YOU WITH ALL THE TESTING THAT'S BEEN DONE. IF THE IND IS APPROVED BY THE FDA, YOU KNOW THAT IT'S FULFILLED ALL THE REQUIREMENTS FDA WOULD HAVE REVIEWED. IS THERE A REASON, OR IS THAT TOO MUCH -- MAYBE YOU DON'T WANT TO BE THAT INVOLVED, BUT DOES SERVE FOR YOU THE PURPOSE THAT THEY HAVE MET ALL THE REGULATIONS AS REQUIRED BY THE FDA. IN ADDITION, IT PROVIDES YOU WITH ALL THE TESTING THAT'S BEEN DONE.

MS. CHARO: I'M SORRY, JOHN. YOU'RE SAYING THAT YOU CAN'T USE FETAL TISSUE WITHOUT AN FDA IND?

DR. WAGER: NOT AS FAR AS I KNOW.

CHAIRMAN LO: CLINICAL TRIALS.

MS. CHARO: IN CLINICAL TRIALS, YEAH, BUT FOR NONCLINICAL TRIALS, YOU WOULDN'T GO TO THE FDA, WOULD YOU?

DR. WAGNER: NO. BUT FOR CLINICAL TRIALS THAT'S WHERE YOU ARE REALLY WORRIED ABOUT TISSUE PRACTICES.

MS. CHARO: THAT'S A GOOD POINT.

CHAIRMAN LO: AGAIN, I THINK WHAT YOU'RE GETTING AT, JOHN, TO WHAT EXTENT ARE WE BEING COUNTERPRODUCTIVE RATHER THAN USEFUL IN SORT OF JUST REMINDING PEOPLE IF YOU ARE GOING TO DO SCREENING TESTS, KEEP A CLOSE RECORD OF -- KEEP A GOOD RECORD OF THEM.

DR. WAGNER: WHAT'S DIFFERENT ABOUT IT, I WOULD SAY THAT IT'S OVERBOARD, BUT IN THIS CASE YOU ARE PROVIDING FUNDING FOR SUCH RESEARCH. AND I THINK THAT IF PART OF WHAT YOUR MANDATE IS IS TO VERIFY THAT THE RESEARCH IS DONE UNDER WHAT YOU CONSIDER TO BE BEST PRACTICES, THIS IS AT LEAST SOMETHING THAT'S A QUICK -- IT DOESN'T ADD ANY WORK, IT PROVIDES YOU ALL THE INFORMATION THAT YOU WANT, AND, FINALLY, THE

REASSURANCE THAT ALL THE REGULATIONS HAVE BEEN MET PROPERLY. REMEMBER, YOU'RE NOT SAYING THAT YOU HAVE TO WRITE AN IND. WHAT YOU'RE SAYING IS IF AN IND IS WRITTEN OR BECAUSE IT WILL BE USED CLINICALLY, THEN IT HAS ACHIEVED ALL THE ELEMENTS THAT YOU ARE LOOKING FOR. AND IT'S ALREADY DONE. ALL THEY'RE DOING IS PROVIDING YOU OR YOU CAN EITHER SAY YOU WANT TO KEEP A COPY OR THAT YOU HAVE ACCESS TO A COPY SHOULD YOU WANT TO GO BACK AND LOOK.

IT'S NO DIFFERENT THAN WHAT YOU'RE ASKING FOR THE SCREENING TESTS THAT HAVE BEEN DONE. THAT'S WHAT LED ME TO THINK WHY NOT JUST ASK FOR THE IND, AND THEN IT CAPTURES ALL THE ELEMENTS OF WHAT YOU WERE LOOKING FOR.

CHAIRMAN LO: I GUESS THE ISSUE WOULD BE SORT OF AT WHAT POINT IN THE RESEARCH THIS WOULD COME INTO PLAY. I GUESS BEFORE YOU REACH THE IND STAGE, SOMEONE MAY JUST BE DERIVING A FETAL STEM CELL LINE, THINKING THAT, WELL, IF ALL WORKS WELL, WE'D LIKE TO USE IT FOR CLINICAL TRIALS, BUT THEY TO HAVE DO JUST A LOT MORE BASIC RESEARCH AND VERIFICATION FIRST SO THAT THEY WOULD NOT NECESSARILY BE WRITING AN IND OR HAVE AN IND AT HAND WHEN THEY'RE APPLYING FOR CIRM FUNDS FOR THE ORIGINAL DERIVATION.

AND SO I GUESS THE ISSUE IS, GIVEN THAT IF

CIRM IS GOING TO INVEST IN THE DERIVATION OF A LINE, DO WE WANT TO SORT OF ENCOURAGE THE INVESTIGATORS TO AT LEAST HAVE THOUGHT ABOUT WHAT THINGS THEY MAY WANT TO DO TO MAKE IT USABLE FOR CLINICAL TRIALS DOWNSTREAM IF THE RESEARCH IS SUCCESSFUL. SO I GUESS THE QUESTION WOULD BE BEFORE YOU GET TO THE POINT OF GOING TO THE FDA, IF YOU'RE SEEKING CIRM FUNDING, IS THERE SOMETHING THAT WE COULD DO TO KIND OF FLAG THIS ISSUE FOR INVESTIGATORS, BOTH TO HAVE THEM THINK ABOUT WHAT SCREENING THEY MIGHT WANT TO CONTEMPLATE, BUT ALSO TO DO THE RECORDKEEPING. I THINK IT'S AN OPEN QUESTION.

DR. WAGNER: I GUESS IF YOU ARE GOING -- WHY WOULD YOU -- AGAIN, THIS IS COMING DOWN TO, YES, I KNOW YOU WANT TO ENCOURAGE THAT THEY KEEP CERTAIN SCREENING INFORMATION, BUT THAT'S ONLY IF THEY GO TO CLINICAL TRIAL.

CHAIRMAN LO: YOU MAY NOT -- YOU MAY ONLY HAVE A LIMITED WINDOW OF OPPORTUNITY TO SORT OF GET CONTACT INFORMATION ON PEOPLE YOU'LL NEED TO GET THAT SCREENING INFORMATION FROM. IF YOU WAIT TILL YOU'RE ABOUT TO GO INTO A CLINICAL TRIAL, YOU MAY NOT BE ABLE TO GO BACK TO THE PEOPLE WHO YOU NEED TO CONTACT FOR THE SCREENING; FOR INSTANCE, PEOPLE OTHER THAN THE BIRTH MOTHER.

DR. PRIETO: SORT OF WHAT OCCURS TO ME IS IF

WE'RE ANTICIPATING THAT SOMEWHERE DOWN THE ROAD THERE MAY BE A FUTURE CLINICAL APPLICATION, BUT THE RESEARCH WE'RE FUNDING IS WELL UPSTREAM OF THAT, WE DO WANT TO ENCOURAGE PEOPLE TO KEEP ADEQUATE RECORDS SO THAT THOSE CLINICAL TRIALS WOULD BE FEASIBLE. I THINK IF THERE ISN'T THAT KIND OF RECORDKEEPING KEPT, THEN DOWNSTREAM THE PRODUCT MAY NOT BE USABLE.

MS. CHARO: THIS IS A PHENOMENON THAT'S GOING TO REALLY HAVE -- THIS IS MOST APPLICABLE AT THE POINT OF COLLECTION OF MATERIALS. AND IN MANY WAYS THAT'S GOING TO BE AT THE CLINICAL SETTING WHERE THE EMBRYOS ARE BEING DEVELOPED AND THEN DISCARDED. IT MAY BE THAT -- I FORGET WHO IT WAS THAT SAID PERHAPS IN THE GRANTING PROCESS, SOME EXPLANATORY MATERIAL ABOUT THINGS TO CONSIDER WOULD BE MOST APPROPRIATE BECAUSE BEFORE THE INVESTIGATOR ACTUALLY BEGINS THE COLLABORATION WITH THE CLINICAL SITE, THAT WOULD BE THE CONVERSATION THAT THE INVESTIGATOR WOULD HAVE TO HAVE. ANY KIND OF MEMOIR THAT YOU ADD TO THE GRANTS APPLICATION PROCESS OR TO THE GRANT APPROVAL LETTER WOULD BE SUFFICIENT.

CHAIRMAN LO: I THINK WE SHOULD CERTAINLY TALK TO THE GRANTS PEOPLE TO SEE IF THEY FEEL COMFORTABLE HAVING THAT AS SOMETHING IN THE GRANT, THE RFP, I GUESS, SOMETHING THEY WANT TO SEE WITHOUT --

MS. CHARO: BERNIE, IT DOESN'T EVEN HAVE TO BE ANYTHING IN REGULATION OR IN THE RFP. THERE'S NO REASON WHY, AS A MATTER OF PRACTICE, OUTSIDE OF REGULATIONS, THAT A GRANTING AGENCY CAN'T INCLUDE IN THEIR LETTER WHAT KIND OF POINTS TO CONSIDER. AS FAR AS THE GRANT REVIEW, SURE, THE GRANT REVIEW PROCESS, I WOULD PRESUME THAT THE GRANT REVIEWERS ARE NOT GOING TO SAY YES TO A GRANTEE WHO PROPOSES TO DERIVE LINES THAT MAY EVENTUALLY HAVE THERAPEUTIC TRANSPLANT APPLICATIONS IF THE GRANTEE HAS NOT PUT IN PLACE A PLAN FOR COLLECTING NECESSARY INFORMATION ABOUT ORIGINAL TISSUE DONORS.

CHAIRMAN LO: YEAH. I MEAN IF IT CAN BE DONE SOLELY THROUGH THE GRANT-MAKING PROCESS WITHOUT REQUIRING REGULATION, THERE'S SOME ATTRACTION TO THAT. SO LET US TAKE THAT TO THE GRANTS PEOPLE AND SEE HOW THEY FEEL ABOUT THAT AND IF THEY'RE SUPPORTIVE AND THEY CAN SAY, YES, WE DON'T NEED FOR YOU TO PUT ANYTHING IN REGULATION AS OPPOSED TO WHATEVER. SCOTT.

MR. TOCHER: I GUESS MY REACTION WOULD BE IF THIS IS -- TYPICALLY ITEMS IN AN RFP ARE SPECIFIC TO THAT PARTICULAR GRANT, SOMETHING THAT IS UNIQUE TO THAT PARTICULAR GRANT OR COUPLE OF GRANTS. AND SO THAT MIGHT BE AN APPROPRIATE VEHICLE.

IF IT WAS SOMETHING, HOWEVER, THAT ACTUALLY

HAD SORT OF BROADER, MORE UNIFORM APPLICATION ON GRANTS ACROSS THE BOARD, THEN IT PROBABLY WOULD NOT SUFFICE. THEN IT WOULD BECOME SORT OF AN UNDERGROUND REGULATION. IT WOULD BE A STANDARD THAT'S BEING APPLIED TO A BROAD CLASS ALMOST UNIFORMLY IN A CONSISTENT BASIS. SO I GUESS IT WOULD DEPEND, THEN, ON REALLY HOW OFTEN, HOW UNIQUE THIS PARTICULAR CRITERIA IS. IT SOUNDS AS THOUGH IT WOULD BE SOMEWHAT UNIQUE TO SPECIFIC TYPES OF GRANTS, BUT I'M NOT -- I DON'T HAVE THE EXPERTISE TO ANSWER THAT.

CHAIRMAN LO: I GUESS IT DEPENDS ALSO ON HOW THE GRANT-MAKING PROCESS IS GOING TO RUN. IF THEY'RE JUST GOING TO HAVE TOTALLY OPEN APPLICATIONS AS OPPOSED TO SPECIFIC GRANTS TO DERIVE NEW STEM CELL LINES, YOU MAY NOT BE ABLE -- YOU'RE JUST GOING TO GET THINGS COMING IN THE DOOR AND NOT KNOW -- NOT HAVE A WAY OF TELLING PEOPLE WHAT THE REQUIREMENTS ARE.

MR. TOCHER: RIGHT.

CHAIRMAN LO: IT SOUNDS LIKE MAYBE, GEOFF, WE SHOULD TRY AND TALK TO ARLENE AND THE GRANTS PEOPLE ABOUT THIS AND SEE IF THIS PROVISION IS NEEDED IN 100200; AND IF THEY FEEL STRONGLY IT'S NOT NEEDED, THEN WE MAY WANT TO OMIT IT FROM WHAT'S BEING PUT OUT FOR PUBLIC COMMENT. OR DO YOU WANT TO JUST PUT IT OUT FOR PUBLIC COMMENT?

DR. LOMAX: WHY DON'T FOLKS TAKE A LOOK AT THE LANGUAGE. THE LANGUAGE IN 100200 IS -- AND I WILL -- AGAIN, I WILL CIRCULATE THAT IMMEDIATELY AFTER THIS CALL WHILE IT'S FRESH. IT'S RELATIVELY TAME. IT JUST SAYS IF YOU'VE DONE IT, WE MIGHT WANT TO TAKE A LOOK AT IT. WE DON'T WANT TO REQUIRE THEM TO REPORT IT TO US BECAUSE THAT THEN SORT OF REQUIRES US TO CREATE A WHOLE NEW SORT OF COLLECTION INFRASTRUCTURE. ALL IT SIMPLY SAYS IS IF YOU'VE DONE ANY TESTING PURSUANT TO FDA AROUND THESE SAFETY ISSUES, WHICH FOR THE MOST PART ARE INFECTIOUS DISEASE, THEN WE MAY WANT TO ASK YOU ABOUT THAT IN THE FUTURE.

SO THERE'S NO SORT OF MANDATORY THOU SHALT REPORT. IT'S ONLY THAT IF THOU HAS HAD TO TRIGGER THIS FDA REQUIREMENT, THEN WE MIGHT COME BACK AND ASK YOU ABOUT IT IN THE FUTURE BECAUSE WE ACTUALLY GET INTO TROUBLE IF WE START CREATING MANDATORY REPORTING REQUIREMENTS AND DON'T HAVE SOME SORT OF SYSTEM FOR INTAKE. AND WE DON'T WANT TO CREATE ADDITIONAL SYSTEMS FOR INTAKE. WE'RE ALMOST OVERLOADED ON THAT FRONT ALREADY.

AGAIN, I WILL CIRCULATE THAT, BUT IT WAS JUST TO ACCOMPLISH THAT SORT OF THRESHOLD GOAL OF SORT OF RECOGNITION THAT THERE ARE FDA REQUIREMENTS OUT THERE WITHOUT, AGAIN, GOING INTO ANY SORT OF MANDATORY

REPORTING SCHEME.

AND, AGAIN, THIS WAS GETTING BACK AT -- WE ORIGINALLY DID HAVE LANGUAGE IN THE REGULATIONS THAT SAID WE WANTED TO KNOW WHAT YOU'VE DONE IN THE AREA OF SAFETY SCREENING, SO WE DIDN'T TRY TO CREATE A NEW REGULATION HERE. WE TRIED TO TAKE THE EXISTING LANGUAGE AND MAKE IT PALATABLE TO THE OFFICE OF ADMINISTRATIVE LAW. SO IF THE WORKING GROUP FEELS THAT THAT LANGUAGE IS NO LONGER SORT OF WARRANTED, THEN WE SHOULD BRING IT BACK AND GO THROUGH THE COMMITTEE PROCESS AND SAY WE NO LONGER BELIEVE THAT LANGUAGE IS NECESSARY. SO WE'RE NOT TRYING TO DO ANYTHING NEW; WE'RE JUST TRYING TO MAKE WHAT WE'VE ALREADY GOT RIGHT FOR REGULATORY PURPOSES.

CHAIRMAN LO: SO IT SOUNDS LIKE WHEN WE CIRCULATE THIS 100200, ONE THING THAT WE'D WANT SOME FEEDBACK ON IS WHETHER YOU THINK THAT THIS PARTICULAR PROVISION, WHICH YOU'LL SEE LATER TODAY, REALLY SHOULD BE DELETED OR NOT. AND THE SECOND ISSUE IS WHETHER, BEFORE IT GETS POSTED, WE SHOULD CHECK BACK WITH THE GRANTS GROUP AS TO WHETHER THEY THINK IT'S UNNECESSARY IN THE SENSE THEY CAN ACCOMPLISH THE SAME THING THROUGH THE GRANTS PROCESS.

AND THE ISSUES THAT JOHN AND ALTA RAISED, IF WE DON'T NEED A REGULATION, BUT CAN ACCOMPLISH THE SAME

GOAL ANYWAY, THAT'S CERTAINLY SOMETHING WE WANT TO THINK ABOUT. SO LET'S SORT OF ADOPT THAT STRATEGY AS WE MOVE FORWARD.

DR. LOMAX: SURE. AND I WOULD ASK FOLKS. WE ARE A BIT TIGHT WITH REGARD TO NEEDING TO GET THIS REGULATION POSTED. SO PEOPLE TAKE A LOOK AT THIS AND REALLY FEEL SOMEHOW WE DON'T NEED THAT LANGUAGE IN REGULATION, PLEASE LET ME KNOW AS SOON AS POSSIBLE BECAUSE WE DO HAVE A DEADLINE TO GET THAT POSTED SO WE CAN GET IT APPROVED BY THE ICOC IN DECEMBER. WE START TO TRIGGER A SERIES OF TIMELINES.

DR. WAGNER: CAN I MAKE ONE MORE COMMENT? ONE THING THAT WE DON'T WANT TO FORGET IS THINK ABOUT IT FOR A SECOND. WHEN WE TALK ABOUT EMBRYOS, WE'RE IN A DIFFERENT CIRCUMSTANCE THAN WE'RE TALKING ABOUT FETAL TISSUE. THE FETAL TISSUE IS GOING TO BE DONE -- WE'RE GETTING THIS TISSUE FROM AN ABORTION CLINIC. WHAT INFORMATION ALREADY EXISTS IN THE ABORTION CLINIC? AND I DON'T KNOW. I DON'T KNOW WHAT THAT INFORMATION IS. I DON'T KNOW WHAT KIND OF TESTING IS DONE ON THESE WOMEN BEFORE AN ABORTION IS PERFORMED. BUT AS AN INVESTIGATOR, THEORETICALLY, IF YOU WERE COLLECTING THAT FETAL TISSUE, I WOULD HAVE MADE SOME ARRANGEMENT. I HAVE NOTHING TO DO WITH THE ABORTION ITSELF. I MAKE ARRANGEMENTS WITH THAT CLINIC TO GET THE TISSUE. WHAT

IS IT YOU THINK I WOULD BE ASKING THAT I WOULD NEED TO COLLECT THAT I WOULD HAVE THIS ONE OPPORTUNITY AND MAY NEVER HAVE IT AGAIN IF I'M DERIVING SOME CELL LINE FROM THIS FETAL TISSUE? WHAT IS IT I MAY EVEN BE ABLE TO ASK FOR SINCE I'M NOT GOING TO BE INTERACTING WITH THIS WOMAN AT ALL?

FOR EXAMPLE, IF YOU WERE ASKING FOR A GENETIC HISTORY OR SOME INFECTIOUS DISEASE SCREENING OR WHATEVER, WHAT IS IT THAT AN ABORTION CLINIC WOULD BE CAPABLE OF DOING? I GUESS WE HAVE TO THINK -- MY POINT IS WE HAVE TO THINK ABOUT THE SPECIFIC SCENARIO OF FETAL TISSUE, WHICH IS VERY DIFFERENT THAN COLLECTING CORD BLOOD OR VERY DIFFERENT THAN COLLECTING EMBRYOS. THIS ONE IS UNIQUE IN THAT IT'S UNDER A DIFFERENT CIRCUMSTANCE WHERE THE WOMAN COMES IN. THERE'S NO TIME TO GO BACK AND THINK ABOUT LIKE WE WERE SUGGESTING WITH EMBRYO RESEARCH. HERE YOU'RE GIVEN THIS BRIEF WINDOW OF OPPORTUNITY, AND WE'RE NOT EVEN DIRECTLY INTERACTING WITH THAT CLINIC OR THAT PATIENT. WE'RE RELYING ON THE CLINIC STAFF TO PROVIDE SOMETHING TO US.

I GUESS MY FEELING IS THAT, WHAT ARE WE WORRIED ABOUT, THAT THE FDA MIGHT LATER COME BACK AND ASK US THAT WE WOULD HAVE TO CAPTURE AT THAT MOMENT?

MS. CHARO: JOHN, FIRST, I THINK THAT'S AN INCREDIBLY SAVVY COMMENT. WE ALL KNOW WHAT THE FDA IS

LOOKING FOR. THEY'RE LOOKING FOR PRIMARILY INFECTIOUS DISEASE INFORMATION ABOUT THE TISSUE DONORS. AND IN THIS CASE, PRESUMABLY, IT WOULD BE THE MALE PARTNER, WHICH IS A VERY DIFFICULT THING TO ASK IN THE ABORTION CLINIC CONTEXT. I KNOW THAT WE HAVE NO INTENTION OF ALTERING CLINICAL CARE PATTERNS IN ANY WAY.

IT DOES SEEM TO ME THAT WE MIGHT -- FINALLY, WE'RE AT A SLIGHTLY DIFFERENT SITUATION, I THINK, THAN IN THE ORDINARY FETAL TISSUE RESEARCH SETTING WHERE IT'S DIRECT TRANSPLANTS BECAUSE HERE WE'RE TALKING ABOUT POTENTIALLY DERIVING LINES FROM EMBRYONIC SPERM CELLS. IS THAT IT? IF IT'S JUST STRAIGHT FETAL TISSUE, IT'S NOT PLURIPOTENT TISSUE, IT WOULDN'T BE COVERED UNDER THE CIRM REGS. I'M IMAGINING WE'RE TALKING ABOUT FETAL TISSUE FOR THE DEVELOPMENT OF STEM CELL LINES, CORRECT?

DR. WAGNER: RIGHT.

MS. CHARO: I'M HAVING A LITTLE TROUBLE FIGURING OUT WHY YOU WOULD NEED MORE THAN THE INFECTIOUS DISEASE, WHY YOU WOULD NECESSARILY NEED THE ADDITIONAL GENETIC INFORMATION FROM THE FATHER. BUT IT MIGHT BE A GOOD THING TO START BY ASKING WHAT IS CURRENTLY THE PRACTICE WITH REGARD TO THE MALE PARTNER. THERE'S VERY FEW RESEARCHERS THAT ARE DOING WORK ON FETAL TISSUE TRANSPLANT. THERE ARE A FEW. AND OF

THOSE FEW, SOME OF THEM ARE WORKING WITH TISSUE FROM MISCARRIED FETUSES WHERE THE MALE PARTNER IS OFTEN EASIER TO IDENTIFY AND IT'S LESS SORT OF POLITICALLY TOUCHY TO ASK ABOUT HIS IDENTITY. BUT THERE MUST BE SOMEBODY WHO'S DOING WORK WITH ABORTED FETUSES, AND WE CAN FIND OUT EXACTLY WHAT THE PRACTICE IS BEFORE WE START WADING INTO THIS AREA.

CHAIRMAN LO: WELL, I THINK THESE ARE GOOD COMMENTS IN THE SENSE THAT MAYBE WE SHOULD DEFER THIS UNTIL WE HAVE MORE INFORMATION ABOUT, FIRST, WHAT IS CURRENTLY BEING DONE AND, SECONDLY, WHAT THE CONCERNS MIGHT BE.

IF YOU GO BACK TO JOHN'S QUESTION, I THINK THE ISSUE IS EXACTLY WHETHER IF THERE'S ANY NEED TO DO ANY SCREENING ON THE MALE PROGENITOR, YOU WOULD NEED -- YOU HAVE A VERY LIMITED WINDOW OF OPPORTUNITY TO GET CONSENT TO CONTACT THAT PERSON. I GUESS THE CHOICE WOULD BE EITHER YOU SAY WE DON'T THINK ANY CONTACT IS NEEDED BECAUSE WE DON'T INTEND TO DO ANY TESTING OR QUESTIONING AT ALL, OR IF YOU SAY TO LEAVE THE DOOR OPEN TO BEING ABLE TO GO BACK AND ASK QUESTIONS OF EVEN BASIC FAMILY GENETIC HISTORY. IF THERE'S A STRONG FAMILY HISTORY OF, FOR EXAMPLE, MALIGNANCY IN THE ORGAN TO WHICH YOU HOPE TO DERIVE ORGAN-SPECIFIC CELLS FROM THE PLURIPOTENT STEM CELL LINE, ONE COULD RAISE THE

QUESTION: DO YOU WANT TO AT LEAST BE ABLE TO ASK THAT QUESTION? AND YOU'RE RIGHT. THAT WOULD REQUIRE WORKING THAT OUT AT THE TIME THE FETAL TISSUE IS OBTAINED.

DR. WAGNER: FIRST OFF, WHAT WE LEARNED WITH CORD BLOOD, WHICH IS INFINITELY EASIER BECAUSE OF ALL THE OTHER TISSUES ASSOCIATED WITH FETAL TISSUE, EVEN WITH CORD BLOOD, WE DON'T HAVE ACCESS TO THE FATHER A SIGNIFICANT PROPORTION OF THE TIME, AND THE MOTHER IS CERTAINLY NOT A GOOD HISTORIAN FOR A FATHER'S GENETIC HISTORY.

SECONDLY, WHAT WE ALSO LEARNED IS THAT MOST OB UNITS FOR CORD BLOOD COLLECTION HAVE NO IDEA HOW TO TAKE A GENETIC HISTORY. ONE OF THE REASONS WHY CORD BLOOD BANKING IS AS EXPENSIVE AS IT IS IS THAT YOU SPECIFICALLY HAVE TO TRAIN PEOPLE TO TAKE A VERY EXTENSIVE GENETIC HISTORY. AND SO IF YOU WANT TO DO IT, YOU HAVE TO DO IT RIGHT. AND IF YOU WANT TO DO IT RIGHT, THEN LITERALLY WHAT WE'RE GOING TO BE DOING IS BASICALLY SETTING UP A STANDARD BY WHICH THE CIRM FUNDS CAN BE USED PROBABLY AT SPECIFIC CLINICS WHO ARE TRAINED SPECIFICALLY TO COLLECT THE DATA THAT YOU ARE LOOKING TO COLLECT. I'M NOT SAYING IT'S A BAD THING; BUT ON THE OTHER HAND, IT IS BEING NOW MORE PRESCRIPTIVE IN HOW THE RESEARCHER COULD EVEN CONCEIVE

OF USING THIS MATERIAL TO GO FORWARD.

AND I THINK IT DOES REQUIRE SOME MORE DISCUSSION ABOUT WHAT THE CURRENT PRACTICES ARE BECAUSE I REALLY HAVE NO IDEA ABOUT AN ABORTION CLINIC. BUT ON THE OTHER HAND, I THINK THAT IF YOU ARE GOING TO GO DOWN THAT PATH AND YOU WANT TO BE ABLE TO ENSURE THAT IF YOU ARE USING THE MONEY AND YOUR INTENT IS TO GO TO CLINICAL USE, THEN YOU MAY WANT TO THEN BE MORE PRESCRIPTIVE IN SAYING THIS IS WHAT YOU MUST DO IF YOU ARE GOING TO USE THIS MONEY. I'M JUST THROWING THAT OUT AS A POSSIBILITY. MAYBE THAT'S NOT YOUR INTENT, BUT JUST KNOW THAT THIS IS NOT STRAIGHTFORWARD. THIS IS NOT SOMETHING ANYBODY CAN PICK UP AND DO.

CHAIRMAN LO: NO. NO. NO. I AGREE. I THINK THE ISSUE IS NOT THAT AT THIS POINT WE WANT TO PRESCRIBE WHAT SCREENING NEEDS TO BE DONE. ULTIMATELY THAT'S GOING TO BE AN FDA ISSUE, AND IT WILL DEPEND A LOT, I THINK, ON THE SPECIFICS OF THE TRANSPLANTATION PROTOCOL. I GUESS THE QUESTION IS DO WE WANT AT THIS STAGE TO AT LEAST ENCOURAGE THE INVESTIGATORS DERIVING FETAL STEM CELL LINES TO THINK ABOUT THESE ISSUES AND TO ASK THEMSELVES THE QUESTION. IF THEY'RE ONLY DOING -- I THINK, AGAIN, THE CORD BLOOD ANALOGY IS THERE'S A LOT OF WORK THAT CAN BE DONE THAT'S CLEARLY NOT DIRECTED AT TRANSPLANTATION, BUT IS VERY USEFUL AND

THIS WOULD ALL BE IRRELEVANT.

AND I GUESS THE ISSUE FOR PEOPLE TRYING TO DERIVE FETAL STEM CELL LINES IS WHETHER YOU WANT TO SAY LET'S JUST GET THE LINE, SHOW WE CAN DERIVE IT, SHOW IT THAT CAN DIFFERENTIATE, AND MAYBE DO SOME ANIMAL RESEARCH. AND THEN IF WE'VE DEVELOPED THAT PROOF OF PRINCIPLE, THEN WE HAVE TO GO BACK AND DERIVE A NEW FETAL STEM CELL LINE THAT REALLY CAN BE USED FOR TRANSPLANTATION, BUT ONLY ADDRESS THESE ISSUES AT THAT POINT RATHER THAN TYING UP THE RESEARCH NOW.

SO I GUESS I'M NOT SURE WE'D WANT TO BE TOO PRESCRIPTIVE NOW, BUT TO AT LEAST HAVE THE RESEARCHERS THINK ABOUT IT. WE MAY END UP SAYING, WELL, IF ALL WE'RE ASKING PEOPLE TO DO IS THINK ABOUT IT, THEN IS THAT SOMETHING WE WANT TO DO IN REGULATION AS OPPOSED TO, FOR INSTANCE, THROUGH GRANTS MANAGEMENT.

I TOTALLY AGREE WITH YOU, JOHN. IT WILL REQUIRE PROBABLY CHANGES IN THE WAY THE TISSUE IS DERIVED. JUST AS I THINK WHEN PEOPLE ARE DONATING EMBRYOS NOW FOR FETAL TISSUE RESEARCH, THE TYPE OF CONSENT PROCESS MAY WELL BE DIFFERENT THAN IT WOULD HAVE BEEN BEFORE STEM CELL RESEARCH WAS CONTEMPLATED.

DR. PETERS: ARE YOU SAYING, BERNIE, THAT THE CURRENT FRONTIER OF RESEARCH IS THAT WE'RE LIKELY TO BE USING THIS ON ANIMAL MODELS? WE'RE REALLY NOT ON THE

BRINK OF HUMAN THERAPY OR THINGS LIKE THAT, SO WE DO HAVE A LITTLE WINDOW OF TIME BEFORE WE HAVE TO CONFRONT THAT. AND THAT WE MIGHT WANT TO BE MORE THOROUGH WHEN WE GET TO THE USE OF HUMAN MODELS OR DEVELOPING THERAPIES THAN WE ARE AT THIS CURRENT STAGE. AND, THEREFORE, IT'S BEST TO DO NOTHING AT THIS PARTICULAR POINT?

CHAIRMAN LO: I THINK THAT'S WHAT WE NEED TO THINK ABOUT. THE FDA ACTUALLY HAS APPROVED A PHASE I CLINICAL TRIAL WITH KIDS WITH BATTEN DISEASE USING FETALLY DERIVED NEUROPROGENITOR CELLS. AND THAT'S ACTUALLY BEING DONE AT ONE INSTITUTION AS A PHASE I TRIAL. THIS HAS ALREADY GOTTEN TO THAT LEVEL OF A PHASE I TRIAL.

MS. CHARO: GERON POTENTIALLY WILL BE ANNOUNCING, THEY'RE ONE YEAR AWAY, BUT THEY MOST RECENTLY ANNOUNCED THEY'RE ONE YEAR AWAY FROM A HUMAN CLINICAL TRIAL FOR SPINAL CORD INJURY USING TISSUE DERIVED FROM EMBRYONIC STEM CELLS.

CHAIRMAN LO: SO I GUESS AT THIS POINT, FOLLOWING JOHN'S THOUGHT, I THINK WHAT WE NEED TO DO IS LOOK AT THE LANGUAGE AND SAY IS THIS SOMETHING THAT WE'RE JUST NOT READY TO DEAL WITH, THAT WE NEED A LOT MORE INFORMATION ON BOTH CURRENT PRACTICE AND ON WHAT SPECIFIC INFORMATION ONE MIGHT BE WANTING TO GATHER,

THAT IT REALLY REQUIRES A LOT MORE. MAYBE, ALTA, YOUR COMMITTEE AT NAS MIGHT BE A BETTER PLACE TO DEAL WITH THAT OR MAYBE THIS IS DOWN THE ROAD. SO I THINK WHEN YOU SEE THE SECTION 100200, WHICH REALLY IS DEALING WITH REPORTING REQUIREMENTS, I THINK IT IS WORTH, PARTICULARLY JOHN AND ALTA, TO LOOK AT IT AND SAY IS THIS REALLY CRAFTED TO DO SOMETHING THAT'S WORTH DOING AS REGULATION AS OPPOSED TO TRYING TO DO IT IN SOME OTHER WAY AS IN, FOR EXAMPLE, THE GRANTS PROCESS. OR IS IT JUST THAT WE NEED TO STEP BACK AND SAY BEFORE WE DO ANYTHING, WE NEED A LOT MORE INFORMATION ON THE TOPIC.

WE'LL RELY ON YOU FOLKS FOR YOUR COMMENT. AS GEOFF JUST SAID, IN ORDER TO KEEP UP WITH THE -- THESE ARE INTERIM FETAL TISSUE -- 100200 IS A SEPARATE TIME TRACK, RIGHT, SO IS THERE AS MUCH URGENCY ON THAT AS THE FETAL TISSUE?

DR. LOMAX: WELL, IT'S URGENCY IN THE SENSE THAT WE WANT BOTH TO BE CONSIDERED AT THE DECEMBER ICOC MEETING. FOR THE PURPOSE OF THE FETAL TISSUE REGULATION, WE'RE FINE BECAUSE NOW WE JUST -- WE'LL TAKE THE SENSE OF THE COMMITTEE TO THE ICOC.

THE 100200 IS A BIT MORE COMPLICATED BECAUSE WHAT WE WOULD LIKE TO DO IS ACTUALLY POST REVISED LANGUAGE THIS WEEK. IT NEEDS TO GO THROUGH THAT 15

DAYS PUBLIC COMMENT, AND THEN WHAT WE'D BRING TO THE ICOC WOULD BE REVISED LANGUAGE THAT HAS THE BENEFIT OF PUBLIC COMMENT.

CHAIRMAN LO: SO WORST CASE, IF WE MISSED THE DECEMBER 7TH ICOC MEETING, WHAT HAPPENS TO SECTION 100200?

DR. LOMAX: THEN WE JUST HAVE TO BRING IT BACK TO THE ICOC IN FEBRUARY.

CHAIRMAN LO: IS THERE -- DO THINGS EXPIRE, OR IS THERE A HORRENDOUS REGULATORY --

DR. LOMAX: TO THE BEST OF MY KNOWLEDGE, NO. SCOTT STEPPED OUT OF THE ROOM. BUT IT'S NOT FATAL, BUT I THINK WE DID WANT TO HAVE SOME MINIMAL LANGUAGE IN THE REGULATIONS ABOUT REPORTING. AND I WOULD ENCOURAGE US NOT TO -- I WOULD ENCOURAGE US ACTUALLY TO TAKE A LOOK AT WHAT WE'VE GOT AND DECIDE ON SOMETHING MINIMAL. WE CAN ALWAYS AMEND THE REGULATIONS AND ADD MORE LATER, BUT WE DID HAVE -- IF YOU GO BACK TO THE PROCESS, THERE WAS CONSIDERABLE PUBLIC COMMENT ABOUT -- THERE'S SOME OTHER LANGUAGE IN THERE ABOUT TRACKING STEM CELLS AND GAMETES AND PRODUCTS OF SCNT, WHICH, I THINK, BASED ON THE PUBLIC COMMENT, WE SHOULD NOT OMIT THAT LANGUAGE FOR TOO LONG.

CHAIRMAN LO: WE COULD JUST TAKE THIS SECTION OUT --

DR. LOMAX: THAT'S RIGHT.

CHAIRMAN LO: -- FROM THE DECEMBER 7TH ICOC PRESENTATION AND COME BACK TO IT LATER AFTER WE'VE GOT THE REST OF 100200.

DR. LOMAX: THAT'S RIGHT. I WOULD ENCOURAGE US AT LEAST TO CONSIDER -- AGAIN, THERE WAS SOME BASIC TRACKING OF PRODUCTS OF SCNT DONATED EGGS, WHICH IS ALSO IN THE EXISTING CALIFORNIA LAW THAT'S OUTSIDE CIRM FUNDING. I WOULD SUGGEST, BASED ON THE PROCESS AND THE PUBLIC COMMENT, THAT WE AT A MINIMUM HAVE SOME LANGUAGE THERE. OTHERWISE, I THINK WE OPEN OURSELVES UP TO SOME CRITICISM.

CHAIRMAN LO: I AGREE. THAT WE'RE SORT OF BEING LAX IN SORT OF KEEPING TRACK OF WHAT MATERIAL IS DONATED FOR RESEARCH, WHAT ACTUALLY HAPPENS TO IT.

DR. LOMAX: YES. SO THE BOTTOM LINE IS WE CAN DROP STUFF NOW AND ADD MORE LATER, BUT WE SHOULD PROBABLY HAVE SOMETHING IN PLACE.

CHAIRMAN LO: SO LET'S ASK YOU TO LOOK AT SECTION 100200. FIRST, A LOT OF THINGS JUST WHICH ARE TECHNICAL REVISIONS OF WHAT WAS THERE BEFORE FOR YOUR APPROVAL, HOPEFULLY, WITH ONLY MINOR MODIFICATION. THERE'S ONE THING WE'VE BEEN TALKING ABOUT, I GUESS THE ISSUE IS DO WE WANT TO SEPARATE THAT FROM THE REST OF 100200 AND DEAL WITH THAT AT SOME LATER TIME.

DR. LOMAX: CORRECT.

CHAIRMAN LO: WE'LL DEPEND ON, I GUESS, JOHN AND ALTA PARTICULARLY FOR THAT EXTRA SECTION ON THE RESULTS OF SCREENING TESTS BEING KEPT AND ACCESSIBLE TO CIRM AS NEEDED.

ANY OTHER ISSUES?

DR. LOMAX: THANKS, EVERYONE.

ONE THING I DID FAIL TO MENTION. THE EGG DONOR CONFERENCE WENT EXTREMELY WELL. AND THERE IS AN ARCHIVE ON THE WEB. SO IF FOLKS WOULD WANT LINKS TO THAT, PLEASE LET ME KNOW. WE'RE EXPECTING A REPORT EARLY PART OF NEXT YEAR, I BELIEVE, FROM THE IOM. SO WE'RE LOOKING FORWARD TO THAT. AND OBVIOUSLY WHEN WE HAVE THEIR FINAL REPORT, WE WILL CIRCULATE THAT TO THE WORKING GROUP AS WELL.

MS. CHARO: ONE -- NEVER MIND. SORRY.

CHAIRMAN LO: WHY DON'T YOU SEND ONE TO PEOPLE LIKE ROB AND ANN KIESSLING.

DR. LOMAX: I THINK I SENT THEM, BUT I'LL RESEND THEM WITH THE E-MAIL WITH THE LANGUAGE AND JUST SORT OF DO A GENERAL UPDATE.

CHAIRMAN LO: THANKS, EVERYBODY. WE WILL GET THIS OUT TO YOU.

(THE MEETING WAS THEN ADJOURNED AT 11:29 AM.)

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

CIRM
210 KING STREET
SAN FRANCISCO, CALIFORNIA
ON
NOVEMBER 13, 2006

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
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