

BEFORE THE
SCIENCE SUBCOMMITTEE OF THE
INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE
TO THE
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE
ORGANIZED PURSUANT TO THE
CALIFORNIA STEM CELL RESEARCH AND CURES ACT
REGULAR MEETING

LOCATION: AS INDICATED ON THE AGENDA

DATE: OCTOBER 10, 2011
2 P.M.

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

BRS FILE NO.: 90969

BARRISTERS' REPORTING SERVICE

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BARRISTERS' REPORTING SERVICE

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MONDAY, OCTOBER 10, 2011; 2 P.M.

CHAIRMAN SHEEHY: ARE WE LIVE? SO ARE WE
READY TO START? OS, ARE YOU THERE?

DR. STEWARD: YES, I'M HERE.

CHAIRMAN SHEEHY: OKAY. SO I'LL CALL THE
MEETING TO ORDER. SHALL WE CALL THE ROLL?

MS. BONNEVILLE: JACOB LEVIN FOR SUSAN
BRYANT.

DR. LEVIN: HERE.

MS. BONNEVILLE: MARCY FEIT. MICHAEL
FRIEDMAN.

DR. FRIEDMAN: HERE.

MS. BONNEVILLE: BERT LUBIN.

DR. LUBIN: HERE.

MS. BONNEVILLE: SHLOMO MELMED.

DR. MELMED: HERE.

MS. BONNEVILLE: FRANCISCO PRIETO. PHIL
PIZZO. DUANE ROTH.

MR. ROTH: HERE.

MS. BONNEVILLE: JOAN SAMUELSON.

MS. SAMUELSON: HERE.

MS. BONNEVILLE: JEFF SHEEHY.

CHAIRMAN SHEEHY: HERE.

MS. BONNEVILLE: OS STEWARD.

BARRISTERS' REPORTING SERVICE

1 DR. STEWARD: HERE.

2 MS. BONNEVILLE: ART TORRES.

3 MR. TORRES: HERE.

4 MS. BONNEVILLE: JONATHAN THOMAS.

5 CHAIRMAN THOMAS: HERE.

6 MS. BONNEVILLE: KRISTINA VUORI.

7 DR. VUORI: HERE.

8 CHAIRMAN SHEEHY: WE HAVE A QUORUM?

9 MS. BONNEVILLE: WE DO.

10 CHAIRMAN SHEEHY: GREAT. SO WE HAVE OUR

11 FIRST ITEM IS CONSIDERATION OF THE STRATEGIC

12 PARTNERSHIP COMPONENT OF THE OPPORTUNITY FUND.

13 DR. STEWARD, WOULD YOU FEEL COMFORTABLE CONDUCTING

14 THIS PART OF THE MEETING SINCE YOU HAVE HAD THE

15 OVERLAP WITH THE IP INDUSTRY SUBCOMMITTEE AND RECENT

16 CONTINUITY THERE?

17 DR. STEWARD: SURE. I'D BE HAPPY TO. SO

18 AS EVERYONE PROBABLY KNOWS, THIS IS A CONTINUATION

19 OF THE CONSIDERATION OF THE OPPORTUNITY FUND THAT

20 WAS CREATED BY THE BOARD IN JUNE OF THIS YEAR. JUST

21 A LITTLE BIT OF BACKGROUND.

22 THE FUND HAD THREE COMPONENTS: THE BRIDGE

23 FUNDING COMPONENT, AN EXTERNAL INNOVATIVE PROGRAM,

24 AND A STRATEGIC PARTNERSHIP PROGRAM. WHAT IS MOVING

25 FORWARD TODAY IS THE CONSIDERATION OF THE STRATEGIC

BARRISTERS' REPORTING SERVICE

1 FUNDING PARTNERSHIP PROGRAM.

2 WHAT HAPPENED WAS THAT THAT PROGRAM WAS
3 REFERRED TO THE INTELLECTUAL PROPERTY SUBCOMMITTEE.
4 THE SUBCOMMITTEE REVIEWED IT AND MADE
5 RECOMMENDATIONS FOR SOME MODIFICATIONS AND IS
6 PASSING THOSE RECOMMENDATIONS ON TO THE SCIENCE
7 SUBCOMMITTEE FOR OUR CONSIDERATION TODAY.

8 THE PURPOSE OF THE STRATEGIC FUNDING
9 PARTNERSHIP WAS TO ENHANCE REALLY THE LIKELIHOOD
10 THAT WE WOULD GET TO PHASE III CLINICAL TRIALS AND
11 GET FOLLOW-ON FINANCING FOR THAT TO PROVIDE A
12 POTENTIAL SOURCE OF CO-FUNDING FOR EARLY STAGE
13 THINGS AND TO PROVIDE CIRM-FUNDED PROJECTS WITH
14 ACCESS TO PHARMA AND BIOTECH PARTNERS THAT COULD
15 HELP OUT MOVING THINGS FORWARD TOWARD TRANSLATION.

16 I CAN SUMMARIZE VERY QUICKLY THE
17 MODIFICATIONS THAT THE IP SUBCOMMITTEE MADE TO THE
18 ORIGINAL PLAN. THE MAIN ONE IS THAT THE
19 SUBCOMMITTEE RECOMMENDED ALLOCATING THE FULL \$30
20 MILLION TO THE STRATEGIC PARTNERSHIP FUNDING PROGRAM
21 AND TO RECOMMEND ADDITIONAL ALLOCATIONS FOR THE
22 OTHER OPPORTUNITY FUND PROGRAMS SEPARATELY TO EXPAND
23 ELIGIBILITY TO INCLUDE EARLY STAGE PROJECTS. AND
24 JUST TO FLESH THAT OUT A LITTLE BIT, THE IDEA WAS
25 THAT THIS CONCEPT PLAN WOULD BE EXECUTED INITIALLY

BARRISTERS' REPORTING SERVICE

1 BY A PROGRAM ANNOUNCEMENT, THAT APPLICATIONS WOULD
2 BE ACCEPTED ON A ROLLING BASIS ABOUT TWICE A YEAR,
3 THAT ELIGIBLE PROJECTS WOULD BE BOTH EXISTING
4 PROJECTS IN GOOD STANDING, PROJECTS AT ANY STAGE OF
5 RESEARCH. AND THAT, I THINK, WAS MAYBE A LITTLE BIT
6 DIFFERENT THAN THE ORIGINAL CONCEPT PLAN. AND THAT
7 IS THINGS THAT FALL ANYWHERE BETWEEN BASIC RESEARCH
8 THROUGH AND INCLUDING PHASE II CLINICAL PROOF OF
9 CONCEPT. AND ONLY THOSE PROJECTS THAT HAVE
10 THIRD-PARTY COMMERCIAL VALIDATION WOULD BE
11 CONSIDERED.

12 AND THERE'S A LIST OF THINGS THAT
13 CONSTITUTE VALIDATION WHICH WOULD INCLUDE A TERM
14 SHEET OR LETTER OF INTENT TO PROVIDE FUNDING, A
15 DISEASE FOUNDATION FUNDING, OR OTHER SOURCES OF
16 THIRD-PARTY SUPPORT; FOR EXAMPLE, GOVERNMENT OR
17 SBIR.

18 AGAIN, THE PROPOSAL FROM THE IP
19 SUBCOMMITTEE WAS THAT THE STRATEGIC PARTNER PROGRAM
20 WOULD RECEIVE 30 MILLION WHICH, JUST TO PUT THE
21 NUMBERS IN PLACE, AS I UNDERSTAND IT, THE ORIGINAL
22 AMOUNT WAS 30 MILLION, BUT 5 MILLION OF THAT HAD
23 ALREADY BEEN EARMARKED FOR TECHNOLOGY TRANSFER
24 SUPPORT. SO THERE'S JUST A LITTLE BIT OF MAYBE
25 NUMBERS TO CLARIFY.

BARRISTERS' REPORTING SERVICE

1 THE OTHER ASPECT OF THIS IS THAT THE IP
2 SUBCOMMITTEE RECOMMENDED A MAXIMUM SUPPORT OF 10
3 MILLION, BUT THAT WOULD EXCLUDE FUNDING FOR TECH
4 TRANSFER PATENT SUPPORT, AND THAT PER PROJECT
5 FUNDING COULD BE INCREASED AT THE DISCRETION OF THE
6 IP SUBCOMMITTEE. TERM OF AWARDS FOR FOUR YEARS.

7 AND SO JUST TO LAY THIS OUT, THIS WOULD BE
8 SOMETHING THAT WOULD GO THROUGH THE USUAL REVIEW
9 PROCESS AT CIRM. IT WOULD INCLUDE REVIEW BY THE
10 GRANTS WORKING GROUP. IT WOULD INCLUDE REVIEW BY
11 THE IP SUBCOMMITTEE OF THE PROPOSED TERM SHEETS, AND
12 THEN FINAL REVIEW AND APPROVAL BY THE ICOC.

13 DR. JUELSGAARD: THIS IS STEVE JUELSGAARD
14 AND I'M THE CHAIRMAN OF THE IP SUBCOMMITTEE. AND I
15 THINK OS PRESENTED A REALLY GREAT OVERVIEW, BUT I
16 HAVE A COUPLE THINGS THAT I'D LIKE TO ADD.

17 CHAIRMAN SHEEHY: PLEASE GO AHEAD.

18 DR. JUELSGAARD: I'M SURE YOU'RE
19 WONDERING, TO BEGIN WITH, HOW WE ARRIVED AT THE
20 NOTION OF FUNDING THIS PROGRAM FOR \$30 MILLION ON
21 ITS OWN GIVEN WHERE WE STARTED FROM. I THINK THERE
22 ARE TWO MAJOR REASONS BEHIND THAT. AND BEFORE I
23 DESCRIBE THAT, LET ME JUST SAY THAT ESSENTIALLY WHAT
24 THIS PROPOSAL WOULD REQUIRE IS ESSENTIALLY SEPARATE
25 FUNDING. SO IN ADOPTING THIS PROPOSAL, WE WOULD

BARRISTERS' REPORTING SERVICE

1 NEED TO ALSO AS A BOARD ADOPT SEPARATE FUNDING FOR
2 THE OTHER TWO PROGRAMS THAT WERE PART OF THE
3 OPPORTUNITY FUND; THAT IS, THE BRIDGE FUNDING
4 PROGRAM AND THE EXTERNAL INNOVATION FUNDING PROGRAM.
5 SO THERE WOULD HAVE TO BE ADDITIONAL FUNDING
6 COMMITTED TO THOSE. AND ALSO WE WOULD NEED TO
7 SEPARATELY APPROVE \$5 MILLION FOR THE TECHNOLOGY
8 TRANSFER FUNDING THAT HAS ALREADY BEEN AGREED TO.

9 SO THERE ARE SEVERAL MOVING PIECES THAT
10 WOULD NEED TO BE CONSIDERED CONTEMPORANEOUSLY AT THE
11 BOARD TO MAKE ALL THIS WORK. ESSENTIALLY IT WOULD
12 MEAN THE COMMITMENT OF ADDITIONAL FUNDS ALTOGETHER
13 FOR THESE FOUR DIFFERENT ACTIVITIES.

14 BACK TO WHY WE DECIDED THAT \$30 MILLION
15 DEDICATED TO THIS FUND WAS THE APPROPRIATE THING TO
16 DO. THE FIRST IS THAT IT WAS OUR VIEW THAT IN ORDER
17 FOR THIS PROGRAM TO BE EFFECTIVE, IT'S GOING TO
18 TAKE -- AND THE PROGRAM IS REALLY DESIGNED TO
19 INCENTIVIZE COMMERCIAL ENTERPRISE TO JOIN IN A
20 PROJECT AND TO TAKE A PROGRAM ESSENTIALLY THROUGH
21 PARTICULARLY THE LATTER STAGES OF CLINICAL
22 DEVELOPMENT, ALTHOUGH POSSIBLY EARLIER STAGES AS
23 WELL, TO TAKE ON THE MANUFACTURING RESPONSIBILITIES,
24 REGULATORY APPROVAL, AND THEN ULTIMATELY
25 COMMERCIALIZATION. SO IT'S REALLY DESIGNED TO BE AN

BARRISTERS' REPORTING SERVICE

1 AID TO ATTRACTING COMMERCIAL BUSINESS.

2 IF WE NEVER REALLY NEED TO EMPLOY THIS
3 AID, THEN WE WOULDN'T DO IT, BUT THERE'S A SENSE
4 THAT WE MAY NEED TO AND, HENCE, THE NOTION OF
5 CREATING THE FUND IN THE FIRST PLACE. IF WE DO NEED
6 TO USE IT, BECAUSE THE AMOUNT OF MONEY THAT'S
7 INVOLVED IN THESE PROCESSES WHICH I JUST SPOKE OF IS
8 QUITE CONSIDERABLE IN NATURE, THE BELIEF WAS THAT WE
9 NEED TO HAVE ENOUGH WHEREWITHAL WITH RESPECT TO ANY
10 PARTICULAR COMMERCIAL ENTERPRISE TO REALLY MAKE IT
11 ATTRACTIVE TO THEM. AND THAT'S WHY WE THOUGHT
12 PROBABLY SOMETHING IN THE NEIGHBORHOOD OF \$10
13 MILLION WOULD SERVE THAT PURPOSE, ALTHOUGH I THINK
14 WE ALSO RECOGNIZED THAT IT MIGHT EVEN TAKE MORE. WE
15 HAVEN'T REALLY TRIED THIS OUT WITH ANYBODY ON THE
16 COMMERCIAL SIDE. SO THERE WILL BE A LITTLE BIT OF
17 SEEING HOW IT GOES AT THE BEGINNING.

18 SO THE FIRST ANSWER THAT WE PUT \$30
19 MILLION TO THIS WAS WE FELT THAT WE NEEDED A
20 SUBSTANTIAL SUM OF MONEY IN ORDER TO MAKE THIS
21 WORKABLE AT ALL AND THAT \$30 MILLION SERVED THAT
22 INITIALLY SUBSTANTIAL SUM OF MONEY.

23 THE SECOND REASON, AND THIS IS PROBABLY
24 MORE A REASON THAT I SEE THAN MAYBE OTHERS SEE, BUT
25 I THINK JUST IN THE NATURE OF THE WAY THE

BARRISTERS' REPORTING SERVICE

1 OPPORTUNITY FUND WAS CONSTRUCTED IN THE FIRST PLACE
2 WITH HAVING THREE DIFFERENT PIECES DRAWING MONEY
3 FROM A SINGLE POT CREATES A BIT OF AN INTERNAL
4 CONFLICT ISSUE. SO WHEN YOU'RE OUT TALKING TO
5 SOMEBODY LIKE A COMMERCIAL ENTERPRISE AND
6 NEGOTIATING WITH THEM, AND YOU HAVE DISCUSSIONS AND
7 YOU COMMIT TO PROVIDING A CERTAIN LEVEL OF FUNDING
8 AS PART OF THOSE NEGOTIATIONS, YOU WANT TO BE SURE
9 THAT YOU ACTUALLY HAVE THE WHEREWITHAL TO DELIVER ON
10 THAT AMOUNT OF MONEY. WHAT YOU DON'T WANT TO DO IS
11 MAKE A COMMITMENT AND THEN COME BACK HOME ONLY TO
12 FIND THAT THAT FUND HAS IN THE MEANTIME COMMITTED
13 MONEY ELSEWHERE FOR ONE OF THE OTHER PROGRAMS AND
14 SUDDENLY YOU DON'T HAVE THAT LEVEL OF FUNDING
15 AVAILABLE TO YOU.

16 SO HAVING THREE DIFFERENT FUNDING
17 PRINCIPALS DRAWING FROM THE SAME FUND ALWAYS, AT
18 LEAST FROM MY POINT OF VIEW, HAVE THAT POTENTIAL FOR
19 CONCERN. AND THAT IS THAT YOU REALLY FIND OUT YOU
20 DON'T HAVE THE MONEY AVAILABLE BECAUSE IN THE
21 MEANTIME IT'S GONE IN A DIFFERENT DIRECTION. SO IN
22 ORDER TO AVOID THAT AS A POTENTIAL PROBLEM, AND I'M
23 NOT SAYING IT WOULD NECESSARILY OCCUR, BUT MIGHT
24 OCCUR, AND IN ORDER TO AVOID IT, WE THOUGHT IT BEST
25 TO HAVE THE OPPORTUNITY -- TO HAVE THE STRATEGIC

BARRISTERS' REPORTING SERVICE

1 PARTNERSHIP FUND BASICALLY CALLED OUT SEPARATELY AS
2 ITS OWN SEPARATE PROGRAM WITH ITS OWN SOURCE OF
3 FUNDING SO AS TO AVOID THAT AS A POTENTIAL ISSUE.

4 SO I THINK THOSE ARE THE TWO MAIN POINTS
5 THAT I WANTED TO OUTLINE TO THE OUTLINE OS JUST
6 PROVIDED.

7 CHAIRMAN SHEEHY: COULD I ASK A QUESTION?

8 MR. JUELSGAARD: SURE. I IMAGINE JEFF IS
9 RUNNING THE MEETING.

10 CHAIRMAN SHEEHY: I'M TRYING TO PASS THE
11 CHAIR OFF TO OS, BUT I THINK IT'S BACK IN MY LAP. I
12 WAS GOING TO ASK A QUESTION. MY QUESTION IS IS THE
13 NUMBER -- YOU KNOW, NOW THAT WE'VE KIND OF
14 INTELLECTUALLY SEPARATED THIS FROM THIS 30 MILLION
15 THREE-PIECE PART, IS 30 MILLION SUFFICIENT? HAVE
16 YOU ACTUALLY THOUGHT ABOUT -- YOU'RE TALKING ABOUT
17 \$30 MILLION A PROJECT -- I MEAN \$10 MILLION A
18 PROJECT, TWICE A YEAR. YOU MAY BE THROUGH IT IN THE
19 FIRST TIME YOU GET UP TO THE PLATE.

20 JUST I'VE ALWAYS BEEN WILLING TO EXTEND
21 SOME OF THESE IF THERE'S A SENSE THAT THERE MIGHT BE
22 PROJECTS OUT THERE THAT WOULD BE VALUABLE FOR US TO
23 INVEST IN.

24 DR. JUELSGAARD: JEFF, I'LL ANSWER THAT AT
25 LEAST FROM MY POINT OF VIEW, AND I THOUGHT A LITTLE

BARRISTERS' REPORTING SERVICE

1 BIT ABOUT THAT. I THINK \$30 MILLION IS SUFFICIENT
2 AT THIS POINT, NOT BECAUSE I THINK THAT THAT'S ALL
3 THE DEMAND THAT THERE WILL BE, BUT I THINK IT'S A
4 GREAT PLACE TO START. AND WE REALLY NEED TO SEE HOW
5 THIS IS GOING TO PLAY OUT AND WHAT THE EXPECTATIONS
6 OF PEOPLE ON THE OTHER SIDE WILL BE.

7 AND WHAT I DON'T WANT TO DO IS TO, IN THE
8 FIRST INSTANCE, CAUSE THEM TO HAVE BIGGER EYES THAN
9 WE WOULD LIKE THEM TO HAVE WHEN LOOKING AT FUNDING
10 THAT CIRM MIGHT HAVE. I THINK IF WE SAY WE HAVE A
11 LIMITED FUND, IT'S \$30 MILLION, WE HAVE A LIMITED
12 GRANT AMOUNT, IT'S \$10 MILLION, THAT PUTS A LITTLE
13 BIT OF A DAMPER ON WHAT THEY MIGHT OTHERWISE WANT TO
14 EXPECT OR DEMAND OUT OF ONE OF THESE.

15 NOW, IT MAY TURN OUT THAT THOSE AMOUNTS OF
16 MONEY AT THE END OF THE DAY DON'T SERVE THE PURPOSE
17 FOR WHICH WE'RE HOPING IT WILL, AND THEN WE CAN COME
18 BACK AND REVISIT THIS. BUT I'D RATHER START ON WHAT
19 I WOULD CALL THE SMALLER END. SOME OF YOU MAY NOT
20 THINK THIS IS THE SMALLER END, BUT IT IS FROM MY
21 POINT OF VIEW, SMALLER END AND SEE HOW THIS ALL
22 GOES. IF INDEED IT IS SERVING THE PURPOSE, BUT WE
23 NEED TO EITHER AGREE TO A LARGER POOL TO DRAW FROM
24 OR SOME OTHER CHANGES, WE CAN COME BACK ULTIMATELY
25 TO THE IP SUBCOMMITTEE AND THEN TO THE SCIENCE

BARRISTERS' REPORTING SERVICE

1 SUBCOMMITTEE AND THEN TO THE BOARD IF WE NEED TO DO
2 THAT. I THINK WE CAN DO THIS ON A FAIRLY FAST
3 TURNAROUND BASIS.

4 MS. FEIT: THIS IS MARCY AND I JUST JOINED
5 THE CALL. I AGREE. MY QUESTION WAS THE SAME. IS
6 THERE A WAY THAT WE COULD MAYBE STATE THAT WE WOULD
7 MONITOR THE DEMAND AND, THEREFORE, BE ABLE TO COME
8 BACK AND ASK OURSELVES IF WE NEED TO ADD ANOTHER
9 POOL OR INCREASE THE POOL?

10 DR. JUELSGAARD: SURE. I THINK SO,
11 ASSUMING WE -- IF THE BOARD AGREES TO MAKE THESE
12 CHANGES AND WE ESTABLISH THIS \$30 MILLION FUND AND
13 WE CAN GO OUT AND BEGIN TO TALK TO COMMERCIAL
14 ENTERPRISES ABOUT THEIR INVOLVEMENT IN ONE OR MORE
15 VARIOUS DISEASE TEAM PROGRAMS, AND ASSUMING THAT
16 THAT WOULD GET ALONG. I THINK THE STAFF WHO'S
17 INVOLVED CAN COME BACK AND REPORT TO THE BOARD AS TO
18 WHAT LEVEL OF INTEREST THERE IS, WHAT SORT OF
19 INTEREST IS BEING EXPRESSED BY THE COMMERCIAL
20 ENTERPRISES, WHAT THEIR CONCERNS ARE, AND WE CAN GET
21 NOT ONLY MONITORING IN TERMS OF NUMBERS, BUT
22 MONITORING IN TERMS OF QUALITY AND CONCERN.

23 DR. MELMED: MAY I ASK A QUESTION ON THAT
24 WHILE WE'RE DISCUSSING THIS QUESTION. WHO EXACTLY
25 IS THE RECIPIENT OF THIS GRANT? THE NONPROFIT OR

BARRISTERS' REPORTING SERVICE

1 THE FOR-PROFIT OR BOTH?

2 DR. JUELSGAARD: THIS WILL BE FOR
3 FOR-PROFIT ENTERPRISES.

4 DR. MELMED: SO NONPROFIT CAN'T APPLY FOR
5 THIS?

6 DR. JUELSGAARD: IF A NONPROFIT -- I DON'T
7 KNOW. I DON'T THINK IT'S WRITTEN THAT WAY.

8 DR. MELMED: BUT IT DOESN'T MENTION THAT
9 IN THE DOCUMENTS. I'M TRYING TO UNRAVEL THE TARGET.
10 IT DOESN'T REALLY SAY WHO'S ELIGIBLE TO APPLY OR WHO
11 IS INELIGIBLE TO APPLY.

12 CHAIRMAN SHEEHY: COULD WE MAYBE -- BOTH
13 DR. TROUNSON AND ELONA BAUM HAVE BOTH SIGNALLED.
14 SHOULD WE HEAR FROM THEM?

15 MS. SAMUELSON: I HAVE A QUESTION, JEFF.

16 DR. TROUNSON: I THINK WE'RE RESPONDING TO
17 THE EXTERNAL REVIEW PANEL TO TRY AND IDENTIFY WAYS
18 IN WHICH WE WOULD ENHANCE OUR RELATIONSHIP WITH
19 BUSINESS. SO IT WAS VERY SPECIFICALLY ORIENTATED TO
20 RELATIONSHIPS WITH BUSINESS, SO IT DOESN'T INCLUDE
21 THE NONPROFITS. THE ARGUMENT FROM THE PANEL WAS
22 THAT WE'RE ACTUALLY DOING PRETTY WELL ON THAT BASIS.
23 SO THIS IS REALLY TARGETED TOWARDS THE BUSINESS
24 SECTOR.

25 THE OTHER THING, I'M SUPPORTIVE --

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1 DR. MELMED: WHEN YOU SAY THAT, ALAN, ARE
2 WE EXCLUDING NONPROFITS?

3 DR. TROUNSON: YEAH. I THINK IT WAS VERY
4 SPECIFIED TO ENCOURAGING THE RELATIONSHIP WITH THE
5 INDUSTRIAL, WITH THE BUSINESS SECTOR. SO THIS
6 COMPONENT PART OF THE OPPORTUNITY FUND WAS REALLY
7 ORIENTATED VERY DIRECTLY TOWARDS THAT END.

8 AND JUST AN ADDITIONAL COMMENT. I THINK
9 IT'S USEFUL IN THE BEGINNING IF IT'S \$30 MILLION
10 BECAUSE IT ENABLES US TO GET THOSE BUSINESSES THAT
11 WANT TO SORT OF CO-FUND WITH US AN AREA, ESSENTIALLY
12 CO-FUND A PROJECT AREA THAT WOULD -- IF YOU HAVE IT
13 TOO LARGE, YOU ACTUALLY DISPERSE THE WAY YOU GO
14 ABOUT NEGOTIATING WITH THEM. BUT ESSENTIALLY IF
15 THERE'S A LIMITED NUMBER IN THE FIRST PLACE, YOU CAN
16 ACTUALLY GET THOSE PEOPLE WHO ARE REALLY KEEN TO
17 JOIN RELATIVELY QUICKLY.

18 SO I THINK IT'S A GOOD STRATEGY TO HAVE IN
19 THE FIRST PLACE A LIMITED AMOUNT OF FUNDS. AND IF
20 IT LOOKS VERY ENCOURAGING, THEN WE SHOULD EXPAND IT.

21 LET ME BE CLEAR ABOUT IT. THIS IS
22 RESEARCH THAT WOULD BE -- THIS WOULD BE MONEY THAT
23 WOULD COME FROM TWO SOURCES, CIRM AND FROM THE
24 BUSINESS SECTOR, TO SUPPORT PROJECT AREAS.

25 DR. VUORI: JUST A CLARIFICATION. WHERE

BARRISTERS' REPORTING SERVICE

1 IS THE WORK THEN TO BE CARRIED OUT? IS IT DONE IN
2 THE COMPANY, OR IS IT DONE IN THE NONPROFIT
3 ORGANIZATION?

4 CHAIRMAN SHEEHY: ELONA WANTED TO ADD
5 SOMETHING.

6 MS. BAUM: I THINK THAT THE REASON WHY
7 IT'S NOT SPECIFIED IN THE CONCEPT IS BECAUSE, ONE,
8 IT'S A CONCEPT WHICH WILL ALLOW US TO BE MORE
9 SPECIFIC WHEN WE DO THE PROGRAM ANNOUNCEMENT. ONE
10 VISION AND ONE MODEL THAT COULD WORK IS THAT YOU'RE
11 ACTUALLY AWARDING IT TO A CURRENT GRANTEE WHO COULD
12 BE A NONPROFIT WHO THEN SEEKS TO ENTER INTO A
13 THREE-WAY AGREEMENT WITH CIRM AGREEING TO FUND A
14 CERTAIN AMOUNT OVER A PERIOD OF TIME AND WITH PHARMA
15 AGREEING TO FUND A CERTAIN AMOUNT OVER TIME. BUT
16 THE AWARD WOULD BE TO, FOR INSTANCE, OR COULD BE TO
17 THE NONPROFIT GRANTEE, BUT THERE WOULD BE THIS
18 UNDERLYING AGREEMENT WHICH THE IP SUBCOMMITTEE COULD
19 APPROVE THE TERMS OF.

20 THIS IS OFTEN DONE AND IT'S CALLED AN
21 OPTION AGREEMENT WHERE THE PHARMA WOULD HAVE AN
22 OPTION AFTER, FOR INSTANCE, PHASE II OF TAKING THE
23 WHOLE PROJECT AND FUNDING IT ALL THE WAY TO PHASE
24 III. SO WE WANTED TO LEAVE THAT ABILITY TO MODEL AN
25 AGREEMENT IN THAT WAY, WHICH IS WHY THAT WE ARE NOT

BARRISTERS' REPORTING SERVICE

1 AS DESCRIPTIVE AS TO THE DIFFERENT MODELS THAT WOULD
2 BE FUNDED.

3 CHAIRMAN SHEEHY: OTHER QUESTIONS? DOES
4 THAT ANSWER YOUR QUESTION, DR. VUORI?

5 DR. VUORI: YES, I THINK SO. IF I
6 UNDERSTAND CORRECTLY, IT COULD BE ESSENTIALLY,
7 DEPENDING ON HOW THE PUBLIC PROJECT PLAN IS
8 STRUCTURED, THERE COULD BE WORK PROBABLY GOING ON IN
9 THE ACADEMIC LABORATORY IN THE COMPANY, THERE COULD
10 WORK PROJECT AT SOME POINT IN TIME AND CERTAIN
11 MILESTONES HAVE BEEN MET TO A COMPANY ALTOGETHER. I
12 GATHER THIS IS THE IDEA.

13 MS. BAUM: EXACTLY.

14 MR. JUELSGAARD: LET ME JUST ADD A LITTLE
15 BIT OF COLOR TO THAT. SO THERE WILL BE THREE
16 IMPORTANT END GAMES THAT NEED TO BE DEALT WITH
17 BEFORE A PRODUCT WILL BE ABLE TO COME TO THE
18 MARKETPLACE. THEY WILL INCLUDE PHASE III CLINICAL
19 DEVELOPMENT, WHICH IS LARGE-SCALE CLINICAL
20 DEVELOPMENT, GENERALLY OPERATING THROUGH SEVERAL
21 CLINICAL CENTERS IN WHATEVER JURISDICTIONS ARE
22 SELECTED, AND THEY ALL HAVE TO BE OVERSEEN AND
23 COORDINATED THROUGH A SINGLE BODY THAT ADDRESSES
24 THOSE CLINICAL TRIALS.

25 SO TYPICALLY COMPANIES HAVE THAT KIND OF

BARRISTERS' REPORTING SERVICE

1 IN-HOUSE EXPERTISE AND THAT CAPABILITY. THERE ARE
2 GOVERNMENT AGENCIES LIKE THE NIH THAT HAVE,
3 PARTICULARLY IN THE CANCER AREA, GROUPS THAT DO THAT
4 LIKE THE EASTERN COOPERATIVE ONCOLOGY GROUP AND
5 SEVERAL OTHERS. BUT THAT WILL NEED TO BE DONE, AND
6 IT'S PROBABLY NOT SOMETHING THAT A LOT OF SINGLE
7 ACADEMIC CENTERS HAVE HAD. THEY PROBABLY
8 PARTICIPATED IN INDIVIDUAL CLINICAL TRIALS, BUT NOT
9 COORDINATED SEVERAL CLINICAL TRIALS THAT ARE PUT
10 TOGETHER TO FORM THE COMPREHENSIVE PHASE WHEN
11 CLINICAL DATA THAT ARE NEEDED.

12 THE SECOND THING THAT'S GOING TO NEED TO
13 BE DONE IS ADDRESS THE REGULATORY APPROVAL ISSUES,
14 WHICH ARE THERE'S A LOT UNKNOWN ABOUT THAT. AGAIN,
15 MOST OF THAT REGULATORY EXPERTISE AIMED AT BOTH
16 APPROVAL OF THE PRODUCT AND APPROVAL OF THE PROCESS
17 BY WHICH THE PRODUCT IS MADE, THAT REGULATORY
18 EXPERTISE IS GOING TO EXIST WITH INSIDE COMMERCIAL
19 ORGANIZATIONS WHO ARE FAMILIAR WITH THOSE REGULATORY
20 PROCESSES.

21 AND THEN LASTLY, WE'RE GOING TO HAVE TO
22 ADDRESS COMMERCIAL PRODUCTION OF WHATEVER THE
23 PRODUCT IS THAT'S GOING TO BE APPROVED, WHETHER IT'S
24 A STABLE STEM CELL LINE, WHETHER IT'S SOME PROTEIN
25 THAT INTERDICTS AT THE LEVEL OF STEM CELLS OR

BARRISTERS' REPORTING SERVICE

1 WHATEVER WE'RE TALKING ABOUT. AND AGAIN, THAT
2 MANUFACTURING CAPABILITY AND EXPERTISE SUFFICIENT
3 FOR FDA APPROVAL, LICENSURE AND APPROVAL, WILL MOST
4 LIKELY EXIST WITHIN A COMMERCIAL ENTERPRISE.

5 AND SO I THINK THAT'S WHERE THERE'S LIKELY
6 GOING TO BE A HAND-OFF FROM THE ACADEMIC CENTERS TO
7 A COMMERCIAL ENTERPRISE ARE AROUND THOSE THREE
8 ISSUES. AND THEN, OF COURSE, WE ALSO HAVE TO DEAL
9 WITH THE COMMERCIALIZATION ASPECT OF ALL OF THIS.
10 SO, FOR EXAMPLE, WE HAVE, JUST TO BEGIN WITH,
11 REIMBURSEMENT ISSUE AND ESTABLISHING REIMBURSEMENT
12 ON THE PART OF PRIVATE PAYORS AND PUBLIC PAYORS FOR
13 A NEW THERAPY AS WELL AS WHATEVER IS NEEDED TO
14 DISTRIBUTE THIS PRODUCT TO GET IT OUT INTO THE HANDS
15 OF PRACTITIONERS OR DISTRIBUTED TO CENTERS THAT ARE
16 GOING TO ADMINISTER THIS PRODUCT. A LOT OF THAT
17 STUFF YET TO BE DETERMINED.

18 SO I THINK IN ALMOST ALL CASES, I WON'T
19 SAY ALL, BUT PROBABLY ALMOST ALL CASES, IT'S GOING
20 TO BE NECESSARY TO ENGAGE COMMERCIAL INSTITUTIONS TO
21 GET ALL THAT STUFF DONE.

22 CHAIRMAN SHEEHY: DO WE HAVE --

23 DR. LEVIN: COULD I MAKE ONE COMMENT? I
24 THINK EVEN GIVEN ALL THAT, IT'S VERY IMPORTANT THAT
25 WE NOT EXCLUDE NONPROFIT POTENTIAL APPLICANTS TO

BARRISTERS' REPORTING SERVICE

1 THIS. THE WAY THAT THE STRATEGIC PARTNER PROGRAM
2 WAS FIRST BROUGHT UP WAS, AS ELONA JUST DESCRIBED
3 IT, AS A WAY TO TAKE PROMISING NEW IDEAS THAT WERE
4 CIRM-FUNDED, DEVELOPED UNDER, SAY, AN ETA GRANT OR
5 EVEN A BASIC BIOLOGY GRANT AND THAT HAD SOME
6 INTEREST FROM A PRIVATE THIRD PARTY AND BE ABLE TO
7 RAPIDLY MATCH INVESTMENT BY THE BUSINESS ENTITY TO
8 ENABLE IT TO GET DEVELOPED.

9 BUT THERE'S PLENTY OF SITUATIONS WHERE THE
10 MONEY WOULD NEED TO GO THROUGH THE NONPROFIT ITSELF
11 IF THEY WERE STILL RETAINING, FOR EXAMPLE, THE IP
12 RIGHTS OR THAT THEY WERE INTERESTED IN DEVELOPING
13 THE THERAPY INTO A PRODUCT, BUT IT WOULD STILL --
14 THERE WOULD BE A -- THIS IS A WAY TO BETTER ENGAGE
15 INDUSTRY INTO THIS THREE-WAY PARTNERSHIP.

16 GIVEN THAT, I THINK IT'S REALLY IMPORTANT
17 THAT WE DON'T EXCLUDE NONPROFIT FROM BEING AN ACCESS
18 POINT FOR ONE OF THESE GRANTS.

19 DR. JUELSGAARD: LET ME JUST RESPOND TO
20 THAT. I THINK THAT'S FINE, BUT I THINK
21 REALISTICALLY, AGAIN, THIS IS MY POINT OF VIEW, BUT
22 REALISTICALLY, IF WE'RE GOING TO HOPE TO GET
23 THERAPIES ULTIMATELY OUT INTO USE, IN MANY, MANY,
24 MANY CASES WE'LL NEED TO INVOLVE COMMERCIAL
25 ENTERPRISE.

BARRISTERS' REPORTING SERVICE

1 DR. LEVIN: OF COURSE.

2 DR. TROUNSON: IT WILL HAVE TO BE
3 AGREEABLE TO THE RESEARCH TEAM TO ENGAGE IN THIS
4 ANYWAY. SO IF THAT HAPPENED TO BE AN ACADEMIC
5 GROUP, THEY'D HAVE TO BE AGREEABLE TO IT ANYWAY.

6 MS. BAUM: SOME ACADEMICS WILL WANT TO DO
7 A SPIN-OUT COMPANY SOONER THAN OTHERS. SO I THINK
8 WE NEED TO MAINTAIN THE FLEXIBILITY.

9 BUT THE POINT BEING THAT EVEN IF IT'S A
10 SPIN-OUT COMPANY, THEY MIGHT NOT HAVE HIRED IN-HOUSE
11 ALL THE TALENT THEY NEED, WHICH IT MAKES IT
12 BENEFICIAL TO HAVE THEM LINK UP WITH LARGER
13 COMPANIES THAT HAVE ALL OF THAT EXPERIENCE.
14 REIMBURSEMENT DECISIONS NEED TO START MAKING THEIR
15 WAY INTO STUDY DESIGNS AT PHASE II OFTENTIMES, SO
16 THEY WILL NEED TO LINK UP.

17 DR. LUBIN: CAN I ASK A QUESTION NOW?

18 CHAIRMAN SHEEHY: GO AHEAD, BERT.

19 DR. LUBIN: SO I'M A NEW MEMBER OF THE
20 COMMITTEE, AND I HAVEN'T HEARD THE PREVIOUS
21 DISCUSSIONS RELATED TO THIS. IT'S MY UNDERSTANDING
22 THAT WE'RE SUPPORTING AN INVENTION THAT IS UNABLE TO
23 GET OTHER VENTURE CAPITAL DOLLARS TO CONTINUE MOVING
24 IT FORWARD, BUT OUR REVIEW PROCESS FEELS IT'S
25 SCIENTIFICALLY WORTHWHILE AND SHOULD GET DOLLARS

BARRISTERS' REPORTING SERVICE

1 FROM CIRM. IS THAT A NAIVE STATEMENT, OR IS THAT
2 WHAT WE'RE TALKING ABOUT?

3 CHAIRMAN SHEEHY: I THINK ELONA WILL
4 RESPOND TO THAT.

5 MS. BAUM: I WOULD ACTUALLY DISAGREE WITH
6 THAT. ACTUALLY IF THE ENTITY, IF THE NONPROFIT WAS
7 TO DECIDE TO SPIN OUT AND COULD GET VENTURE CAPITAL,
8 THEY WOULD ALSO BE ELIGIBLE FOR THIS AWARD AS WELL.
9 SO THESE ARE NOT JUST ENTITIES THAT CAN'T ATTRACT
10 VENTURE CAPITAL. IN FACT, SOME ACTUALLY BELIEVE
11 THAT KEEPING THEM IN THE INSTITUTION LONGER, AS LONG
12 AS POSSIBLE, MIGHT BE MORE CAPITAL EFFICIENT BECAUSE
13 YOU DON'T HAVE TO HIRE ALL THE CEO, THE CFO, ETC.,
14 ETC. THAT'S ONE VIEWPOINT.

15 MS. SAMUELSON: I HAVE A FOLLOW-ON
16 QUESTION TO THAT, I THINK.

17 CHAIRMAN SHEEHY: GO AHEAD, JOAN.

18 MS. SAMUELSON: I GUESS THAT'S MY QUESTION
19 AS WELL. AND WHERE IN THE PROCESS DOES THAT
20 ASSESSMENT GET MADE? BECAUSE IT PROBABLY WOULDN'T
21 BE IN THE GRANT WORKING GROUP IF THEY'RE SEEING
22 THESE JUST ON A ROLLING BASIS. IT WOULDN'T BE
23 COMPARING THE UNIVERSE OF ACTIVITY, HAVE ANY KIND OF
24 SENSE OF HOW MERITORIOUS A GIVEN GRANT IS AND HOW
25 FAR THE SCIENCE HAS EVOLVED.

BARRISTERS' REPORTING SERVICE

1 I GUESS I KEEP THINKING OF AT THE
2 BEGINNING, AND I THOUGHT UNTIL AT LEAST PRETTY
3 RECENTLY OR UNTIL NOW, THE SENSE WAS THAT THE
4 SCIENCE WASN'T EVOLVED ENOUGH TO BE READY FOR
5 INDUSTRY. AND SO HOW IS IT THAT WE KNOW THAT -- AND
6 SO YOU TRUST THE NORMAL MARKET PROCESS, I GUESS,
7 WHICH PRESUMABLY IT MEANT THE MONEY ISN'T AVAILABLE
8 BECAUSE THE SCIENCE ISN'T READY. HOW DO WE KNOW
9 IT'S READY? AND WHERE HAVE WE MADE THAT ASSESSMENT
10 OR WILL WE IN OUR PROCESS?

11 CHAIRMAN SHEEHY: DR. TROUNSON IS GOING TO
12 RESPOND TO THAT.

13 DR. TROUNSON: THANKS, JEFF. ONE OF THE
14 THINGS, JOAN, THAT IS ATTRACTIVE TO PHARMACEUTICAL
15 COMPANIES AT THE MOMENT, AND WE KNOW THESE PEOPLE
16 ARE VERY INTERESTED, IS THE POSSIBILITY OF JOINING
17 RELATIVELY EARLY AND SAY THEY PUT IN -- LET'S CHOOSE
18 A FIGURE -- THEY PUT IN 10 PERCENT IN THE EARLY
19 STAGES AND THEN BUILD IT UP TO 30 PERCENT OR 50
20 PERCENT TO 90 PERCENT AND TAKE IT OVER BY PHASE II
21 SO THAT THEY'VE GOT A BUILDING -- THEY'RE BUILDING
22 THEIR FUNDING, AND WE'RE PROPORTIONALLY REDUCING OUR
23 FUNDING. SO THERE'S A SORT OF SHARING OF THE RISK,
24 IF YOU LIKE.

25 THAT'S ONE ISSUE WHICH IS IMPORTANT TO GET

BARRISTERS' REPORTING SERVICE

1 THEM ENGAGED. AND THE OTHER THING IS THAT THEY CAN
2 ACTUALLY HELP THE TEAMS BY DOING SOME OF THE REALLY
3 KEY COMPONENT PARTS EARLY ON SO THAT IF THEY DON'T
4 HAVE TO -- YOU DON'T HAVE TO REDO IT IF YOU HAPPEN
5 TO TAKE ON THIS PROJECT BY ITSELF LATER ON.

6 SO YOU SAVE A LOT OF TIME BY PROVIDING
7 ADVICE, BUT ALSO PROVIDING ADDITIONAL CAPACITY.
8 THESE COMPANIES OFTEN HAVE A LOT OF CAPACITY
9 IN-HOUSE, AND THEY CAN PROVIDE THAT CAPACITY TO
10 THESE TEAMS.

11 SO THE ASSESSMENT OF THIS WOULD BE, AS
12 ELONA SAID, IT WOULD BE MULTIFOLD. IT WOULD INVOLVE
13 THE IP BUSINESS SUBCOMMITTEE TO LOOK AT THE
14 CONTRACTUAL ARRANGEMENTS AND THE BUSINESS ENTERPRISE
15 COMPONENT PARTS, AND THE GRANTS WORKING GROUP AS
16 WELL LOOKING AT THE SCIENCE ISSUES. I THINK IT'S
17 ONLY GOING TO BE THOSE SCIENCE PROGRAMS THAT ARE
18 REALLY WELL HEELED AND MOVING FORWARD THAT WILL BE
19 DESIRABLE BY THIS SECTOR ANYWAY.

20 SO IT WILL BE -- I THINK IT WILL REALLY BE
21 QUITE STRAIGHTFORWARD. BUT IT WILL BE THOSE
22 PROJECTS THAT ARE ENHANCED AND OUR ABILITY TO
23 DELIVER THEM REALLY IMPROVED BY HAVING THESE
24 RELATIONSHIPS.

25 MS. SAMUELSON: THANK YOU.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN SHEEHY: ADDITIONAL QUESTIONS?

2 MR. ROTH: JEFF, I'M GOING TO HAVE TO
3 LEAVE. IT'S DUANE, BUT I'LL JUST COMMENT THAT I'M
4 VERY MUCH IN SUPPORT OF THIS PROGRAM. I THINK IT'S
5 WELL THOUGHT OUT, AND IT DOES INVOLVE THE AREA WHERE
6 THERE REALLY ISN'T VENTURE FUNDING GOING IN.
7 THERE'S VERY LITTLE VENTURE CAPITAL BEING INVESTED
8 IN STEM CELLS IN GENERAL AND I COULD SAY IN
9 THERAPEUTICS IN GENERAL, AND ESPECIALLY AT THE EARLY
10 STAGE. SO THIS PROGRAM IS INTENDED TO HELP ENTICE
11 PEOPLE TO PUT SOME MONEY IN, BUT ALSO TO ADD
12 COMPETENCY THAT DR. STEWARD WAS TALKING ABOUT TO
13 MOVE THESE THINGS FORWARD.

14 CHAIRMAN SHEEHY: IS THAT A MOTION?

15 MR. ROTH: I WOULD MAKE A MOTION THAT WE
16 APPROVE THIS RECOMMENDATION.

17 DR. FRIEDMAN: I WILL SECOND IT.

18 CHAIRMAN SHEEHY: IS THERE ANY ADDITIONAL
19 DISCUSSION, OR SHOULD WE MOVE TO A VOTE?

20 DR. FRIEDMAN: IF I COULD JUST MAKE ONE
21 POINT, PLEASE. IT WILL ONLY TAKE A MOMENT. I LIKE
22 THE IDEA OF BEGINNING WITH A MODEST AMOUNT, THE \$30
23 MILLION. I'D LIKE TO THEN BEFORE -- WE WILL ALSO
24 SEE WHAT IDEAS ARE OUT THERE AND HOW THIS IS
25 RECEIVED. I THINK THAT'S FINE. BUT I THINK WE ALSO

BARRISTERS' REPORTING SERVICE

1 WANT TO LOOK CAREFULLY AND BE CRITICAL OF HOW WE USE
2 THE MONEY AS WE COME AROUND TO THE NEXT TIME THAT WE
3 MIGHT WANT TO REAUTHORIZE OR PERHAPS ENLARGE THIS
4 PROGRAM.

5 I THINK IT'S A VERY USEFUL EXPERIMENT, AND
6 I SUPPORT IT, BUT I THINK WE OUGHT TO LOOK
7 CRITICALLY AT IT BEFORE WE DO IT AGAIN.

8 CHAIRMAN SHEEHY: ANY OTHER BOARD
9 COMMENTS?

10 DR. VUORI: I'M VERY SUPPORTIVE OF THIS
11 APPROACH AS WELL. JUST WANTED TO MAKE ONE COMMENT
12 OR QUESTION MAYBE FOR ELONA PRIMARILY. AND THAT IS
13 THAT WHAT I DEFINITELY AGREE WITH, ESPECIALLY WITH
14 DUANE, IS SORT OF UTILIZING CIRM AND THE PRIVATE
15 SECTOR IN LIEU OF VENTURE CAPITAL FUNDING, IF YOU
16 WILL, AND MOVING DISCOVERIES FORWARD IN THE PRIVATE
17 SECTOR, AND PARTICULARLY THAT WE INVOLVE THEN SOME
18 SORT OF A LICENSING TRANSACTION COMING FROM THE
19 ACADEMIC LAB IN THIS CASE, MANY TIMES A NONPROFIT
20 SECTOR.

21 NOW, MOST OF THE NONPROFIT ORGANIZATIONS
22 AND I THINK CIRM FUNDING AS WELL COMES FROM
23 TAX-EXEMPT BONDS. AND THERE ARE CERTAIN IRS RULES
24 AND REGULATIONS ABOUT PRIVATE BUSINESS USE, HOW
25 TAX-EXEMPT BONDS -- FACILITIES THAT HAVE BEEN

BARRISTERS' REPORTING SERVICE

1 FINANCED WITH TAX-EXEMPT BONDS CAN OR CANNOT BE USED
2 FOR PRIVATE BUSINESS USE. AND IN THOSE LICENSING
3 TRANSACTIONS, THEN, A CERTAIN SAFE HARBOR RULES THAT
4 RELATE TO THESE NEGOTIATIONS. SO I JUST WANT TO
5 MAKE SURE THAT THE IP SUBCOMMITTEE OR WHOEVER IS THE
6 ENTERPRISE HAS A GOOD HANDLE ON THOSE THINGS SO THAT
7 BOND FUNDING THAT IS TAX-EXEMPT HERE TO START WITH
8 SUDDENLY DOES NOT BECOME TAXABLE FOR THE BOND
9 HOLDERS.

10 CHAIRMAN SHEEHY: J.T. HAS AN ANSWER TO
11 THAT.

12 CHAIRMAN THOMAS: KRISTINA, JUST TO SORT
13 OF CLARIFY, IT'S A LITTLE ESOTERIC, BUT THE BULK OF
14 THE BONDS THAT WE NOW HAVE ISSUED ARE ACTUALLY
15 TAXABLE. THERE WERE PORTIONS THAT WERE TAX-EXEMPT
16 THAT WENT TO FACILITIES. BUT ONCE THAT SORT OF RAN
17 ITS COURSE, WE'RE NOW, FOR EXAMPLE, GOING TO BE IN
18 THE NEXT GO ISSUE, WHICH IS NEXT WEEK, AS A TAXABLE
19 BOND COMPONENT.

20 NOW, HAVING SAID THAT, WE'RE IN THE MIDST
21 OF DISCUSSIONS WITH THE IRS WHERE WE ARE ATTEMPTING
22 TO RECAST THEIR THINKING ABOUT WHAT WE'RE DOING IN A
23 WAY THAT WOULD ULTIMATELY END UP GETTING TAX-EXEMPT
24 STATUS FOR OUR DEBT TO, AMONG OTHER THINGS, REDUCE
25 INTEREST COST, ETC., BUT FOR THE MOMENT WE'RE

BARRISTERS' REPORTING SERVICE

1 PREDOMINANTLY TAXABLE.

2 IT'S LIKE, MR. CHAIR, JUST TO MAKE ONE
3 OTHER COMMENT, WHICH IS IN ADDITION TO THIS, I
4 THINK, BEING A SUBSTANTIVELY VERY PRUDENT PROGRAM
5 THAT EVERYBODY HAS PUT TOGETHER HERE, I WANTED TO
6 NOTE THAT WE'RE SENDING A VERY IMPORTANT AND STRONG
7 MESSAGE TO INDUSTRY THAT WE ARE SERIOUS ABOUT
8 INCREASING THEIR ENGAGEMENTS. AND I'VE HEARD FROM A
9 NUMBER OF PEOPLE CONNECTED TO THE CORPORATE WORLD
10 THAT THEY'RE PLEASED TO SEE THIS. AND I THINK THIS
11 IS AN EXCELLENT PROGRAM FOR US TO PUT IN PLACE. AND
12 I ECHO THOSE WHO NOTED THEY STRONGLY SUPPORT.

13 CHAIRMAN SHEEHY: ANY ADDITIONAL BOARD
14 COMMENTS?

15 MR. ROTH: JEFF, I'M GOING TO GO SO I VOTE
16 YES.

17 CHAIRMAN SHEEHY: WE'LL RECORD YOUR VOTE.
18 I'M GOING TO GO AHEAD.

19 WE HAVE A PUBLIC COMMENT HERE IN SAN
20 FRANCISCO.

21 MR. REED: THIS IS DON REED. I ATTENDED
22 THE WORLD STEM CELL SUMMIT, WHICH, BY THE WAY, WAS
23 VERY WELL REPRESENTED BY CIRM. IT WAS TREMENDOUS BY
24 ALL CONCERNED. BUT ONE OF THE BREAKOUT PANELS WAS
25 ON THE PRESENT CLIMATE TO GET MONEY FOR BIOMED. AND

BARRISTERS' REPORTING SERVICE

1 THE PERSON IN CHARGE OF IT, THE HEAD OF PROTEUS
2 ENTERPRISES, DESCRIBED IT IN ONE WORD. HE SAID
3 BRUTAL. SO I THINK THIS IS HIGHLY APPROPRIATE AND
4 SHOULD BE SUPPORTED.

5 CHAIRMAN SHEEHY: DO WE HAVE ANY MORE
6 PUBLIC COMMENT ON THIS ISSUE?

7 DR. LEWICKI: JOHN LEWICKI FROM ONCOMED
8 PHARMACEUTICALS. AND WE RECENTLY RECEIVED A DISEASE
9 TEAM PLANNING AWARD. AND I WANTED TO EXPRESS FROM
10 OUR VANTAGE POINT, NO. 1, OUR REAL ENTHUSIASM TOWARD
11 WORKING WITH CIRM TO MOVE PRODUCTS FORWARD. WE
12 ACTUALLY HAVE A PRODUCT THAT'S THE SUBJECT OF THE
13 DISEASE TEAM GRANT THAT WE HOPE TO HAVE IN THE
14 CLINIC BY THE MIDDLE OF NEXT YEAR.

15 AND I ALSO WANTED TO SAY THAT I THINK THIS
16 PROGRAM HAS BEEN VERY WELL THOUGHT OUT. WE'RE VERY
17 SUPPORTIVE. AND THE \$10 MILLION THAT HAS BEEN
18 DISCUSSED CAN REALLY ALLOW A PROGRAM TO MOVE FORWARD
19 WHEN IT OTHERWISE MAY NOT HAVE. PARTICULARLY AT
20 THIS PARTICULAR STAGE WHERE VENTURE FUNDING, FOR
21 EXAMPLE, WHICH WAS JUST DISCUSSED, IS VERY TIGHT,
22 VERY DIFFICULT TO OBTAIN. AND SO I THINK THIS
23 STRATEGIC PARTNER PROGRAM IS VERY TIMELY, AND I
24 THINK INDUSTRY UNIFORMLY WILL RESPOND VERY
25 POSITIVELY TO IT.

BARRISTERS' REPORTING SERVICE

1 CHAIRMAN SHEEHY: THANK YOU. ANY OTHER
2 PUBLIC COMMENT EITHER HERE IN SAN FRANCISCO OR AT
3 OTHER SITES? THEN, MARIA, CAN WE CALL THE ROLL.

4 MS. BONNEVILLE: SURE.

5 DR. JACOB LEVIN.

6 DR. LEVIN: YES.

7 MS. BONNEVILLE: MARCY FEIT.

8 MS. FEIT: YES.

9 MS. BONNEVILLE: MICHAEL FRIEDMAN.

10 DR. FRIEDMAN: YES.

11 MS. BONNEVILLE: BERT LUBIN.

12 DR. LUBIN: YES.

13 MS. BONNEVILLE: SHLOMO MELMED.

14 DR. MELMED: YES.

15 MS. BONNEVILLE: FRANCISCO PRIETO. PHIL
16 PIZZO. DUANE ROTH. JOAN SAMUELSON.

17 MS. SAMUELSON: YES.

18 MS. BONNEVILLE: JEFF SHEEHY.

19 CHAIRMAN SHEEHY: YES.

20 MS. BONNEVILLE: OS STEWARD.

21 DR. STEWARD: YES.

22 MS. BONNEVILLE: ART TORRES. JONATHAN
23 THOMAS.

24 CHAIRMAN THOMAS: YES.

25 MS. BONNEVILLE: KRISTINA VUORI.

BARRISTERS' REPORTING SERVICE

1 DR. VUORI: YES.

2 CHAIRMAN SHEEHY: THE MOTION CARRIES.

3 THANK YOU.

4 I DO KNOW THAT WE HAVE -- IS DR. CREASEY
5 HERE? THAT HE HAD TALKED TO JON THOMAS AND WANTED
6 TO MAKE A PUBLIC COMMENT HERE TODAY, AND WE'LL DO
7 THAT.

8 DR. MELMED: I HAVE TO GO OFF THE LINE.

9 CHAIRMAN SHEEHY: THERE'S NO MORE ACTION
10 ITEMS, SO IF PEOPLE NEED TO GO.

11 DR. CREASEY: MY NAME IS GRAHAM CREASEY.
12 I AM THE PROFESSOR OF SPINAL CORD INJURY MEDICINE AT
13 STANFORD. AND I JUST WANTED TO MAKE SOME COMMENTS
14 WHICH THIS MAY BEAR ON THE PREVIOUS DISCUSSION
15 ANYWAY. YOU KNOW, MY COLLEAGUES, GARY STEINBERG,
16 PROFESSOR OF NEUROSCIENCE AT STANFORD, AND STEVEN
17 MCKENNA, A NEUROCRITICAL CARE PHYSICIAN AT SANTA
18 CLARA VALLEY, JUST A FEW WEEKS AGO PUT IN THE FIRST
19 IMPLANT USING EMBRYONIC STEM CELLS INTO A PATIENT IN
20 CALIFORNIA AS PART OF THE GERON TRIAL. SO WE'RE
21 VERY HAPPY TO BE INVOLVED IN THAT AND VERY
22 APPRECIATIVE OF ALL THAT CIRM HAS DONE TO MOVE THIS
23 FORWARD AND TO GET TO THE POINT OF CLINICAL TRIALS
24 IN HUMANS AND VERY HAPPY TO CONTRIBUTE WHATEVER
25 EXPERIENCE WE GET FROM THIS TO OTHERS TO GET MORE

BARRISTERS' REPORTING SERVICE

1 CLINICAL TRIALS GOING IN CALIFORNIA.

2 I THINK IT'S ALREADY RECOGNIZED, BUT IT'S
3 BEEN BORNE HOME TO US ALL THE MORE THAT THESE TRIALS
4 ARE VERY EXPENSIVE AT THE HUMAN STAGE, PARTICULARLY
5 IF THEY'RE FUNDED EACH ONE INDIVIDUALLY. AND
6 ALTHOUGH THEY'RE COMPLEX, THERE ARE ACTUALLY A LOT
7 OF COMMON FACTORS IN EACH CLINICAL TRIAL. THE
8 REQUIREMENT FOR ACCESS TO PATIENTS, COMMITTED
9 CLINICAL TEAM, GOOD OUTCOME MEASURES, REGULATORY,
10 DATA MANAGEMENT, ALL OF THESE FACTORS ARE OFTEN
11 COMMON FROM ONE TRIAL TO ANOTHER. AND SO WE'RE
12 THINKING THAT THERE MIGHT BE ECONOMIES OF SCALE IF
13 IT WAS POSSIBLE TO THINK IN CALIFORNIA IN TERMS OF
14 HAVING CORE FACILITIES FOR FUNDING MORE THAN ONE
15 CLINICAL TRIAL SO THAT YOU DON'T HAVE TO REPLICATE
16 ALL OF THESE STRUCTURES FOR EVERY CLINICAL TRIAL.

17 SOME OF THESE EXIST IN ACADEMIC MEDICAL
18 CENTERS. SOME WOULD PERHAPS LEVERAGE FUNDING FROM
19 INDUSTRY OR FROM NIH OR OTHER BODIES. BUT BY NOT
20 HAVING TO REINVENT THE WHEEL FOR EVERY TRIAL, WE
21 THINK WE MIGHT BE ABLE TO GET MORE TRIALS DONE IN
22 CALIFORNIA. AS MORE COMPANIES AND MORE PRODUCTS
23 COME DOWN THE LINE, THEY COULD BE FOLDED INTO A
24 MACHINE, WELL-OILED MACHINE, AND COULD RUN THESE
25 CLINICAL TRIALS WITHOUT HAVING TO START FROM SCRATCH

BARRISTERS' REPORTING SERVICE

1 WITH EVERY NEW PRODUCT OR COMPANY.

2 SO WE SIMPLY WANT TO OFFER THE EXPERIENCE
3 WE ARE GETTING OUT OF THE CURRENT CLINICAL TRIAL AND
4 INVITE THE SCIENTIFIC SUBCOMMITTEE TO THINK ABOUT
5 MECHANISMS THAT WOULD FOSTER THESE ECONOMIES OF
6 SCALE PERHAPS, AS AN EXAMPLE, CORE FACILITY FOR
7 CLINICAL TRIALS IN A FEW PLACES IN CALIFORNIA THAT
8 ATTRACT COMPANIES AND PRODUCTS TO THE STATE AND GET
9 ACCESS TO PATIENTS IN THIS STATE TO THESE TRIALS. I
10 THINK THAT WOULD HELP TO FULFILL THE VISION WE ALL
11 HAVE OF BRINGING THESE TREATMENTS TO CLINICAL
12 PRACTICE AND COMMERCIAL AVAILABILITY. SO JUST WANT
13 TO BRING THIS TO YOUR ATTENTION AND INVITE YOUR
14 THOUGHTS ABOUT IT.

15 CHAIRMAN SHEEHY: DR. TROUNSON AND DR.
16 FEIGAL.

17 DR. TROUNSON: I WAS JUST AT STANFORD
18 FRIDAY. ONE OF THE PROPOSALS, ONE OF THE AREAS
19 WE'RE LOOKING AT IS A CONCEPT OF ALPHA CLINICS
20 NETWORKED THROUGHOUT CALIFORNIA. SO WE HAVE NATALIE
21 DEWITT WHO HAS BECOME A SPECIAL PROJECT OFFICER FOR
22 US, AND ELONA AND ELLEN FEIGAL AND MYSELF AND
23 NATALIE HAVE ACTUALLY DEVELOPED A KIND OF BACKGROUND
24 PROPOSAL FOR THIS. AND I THINK THERE WAS A LOT OF
25 INTEREST, FOR EXAMPLE, AT STANFORD ON THIS AND MANY

BARRISTERS' REPORTING SERVICE

1 OTHER PLACES. AND WE'RE STILL WORKING OUT THE
2 MODEL, BUT IT ADDRESSES A LOT OF WHAT YOU'RE TALKING
3 ABOUT.

4 AND I THINK IT'S VERY IMPORTANT IF WE CAN
5 HAVE A NETWORK ACROSS THE STATE, NOT ONLY
6 INSTITUTION, BUT ACROSS THE STATE THAT CAN REALLY
7 UTILIZE THE EXPERIENCE THAT YOU GET IN MOVING THE
8 CELL THERAPIES THROUGH TO CLINICAL TRIALS. AND SO
9 HOPEFULLY I'LL MAKE SURE THAT NATALIE SPEAKS TO YOU,
10 BUT SHE'S OUT THERE TALKING TO A LARGE NUMBER OF
11 PEOPLE. SO WE CAN GET THIS CONCEPT BROUGHT BACK TO
12 THE BOARD IN A WHITE PAPER THAT WE CAN THEN SORT OF
13 MOVE TOWARDS ESTABLISHING, LET'S HOPE, IN THE FUTURE
14 OR NEAR FUTURE SUCH A NETWORK THAT WOULD ADDRESS
15 SPECIFICALLY THE KIND OF THINGS YOU'RE TALKING
16 ABOUT.

17 DR. CREASEY: ABSOLUTELY. THANK YOU. THE
18 NETWORK WOULD BE HELPFUL.

19 DR. FEIGAL: I THINK, BUILDING ON WHAT
20 ALAN HAS SAID, IS THAT WE'RE ALSO TRYING TO LEVERAGE
21 EXISTING NETWORKS; FOR EXAMPLE, THE CLINICAL TRIAL
22 TRANSLATIONAL GROUP, CANCER CENTERS, A VARIETY OF
23 BIG CENTERS THAT ALREADY EXIST SO THAT WE'RE NOT
24 REINVENTING THE WHEEL AND TRYING TO TAKE THE BEST
25 PARTS OF IT. SO WE ARE TRYING TO THINK OF

BARRISTERS' REPORTING SERVICE

1 OPERATIONAL EFFICIENCIES AND THEN ALSO TRYING TO
2 THINK OF WHAT IS A UNIQUE ASPECT FOR STEM CELL-BASED
3 THERAPIES THAT PERHAPS SOME OF THESE CENTERS DO OR
4 DO NOT ACCOMMODATE.

5 SO WE ARE ALREADY THINKING ABOUT TRYING TO
6 MAKE CALIFORNIA A REAL HUB, A REAL CENTER FOR THIS
7 TYPE OF CLINICAL TRIAL TO GO FORWARD.

8 DR. CREASEY: I THINK IT'S A UNIQUE
9 OPPORTUNITY THAT CIRM HAS TO LEVERAGE THE UNIQUE
10 DESTINATIONS OF MEDICAL TRIALS.

11 CHAIRMAN THOMAS: DR. CREASEY AND HIS
12 COLLEAGUES CAME TO MEET WITH ME SEVERAL WEEKS AGO ON
13 THIS TOPIC, AND IT MAKES IMMINENT SENSE TO ME, AND I
14 ACTUALLY ENCOURAGED HIM AS THE NEXT STEP TO COME TO
15 OUR NEXT SCIENCE SUBCOMMITTEE MEETING TO LAY THIS
16 OUT FOR DISCUSSION. SO I FULLY ECHO WHAT ALAN AND
17 ELLEN SAID. THE TIME IS RIGHT FOR SOMETHING LIKE
18 THIS.

19 CHAIRMAN SHEEHY: DON REED. AND OTHER
20 PEOPLE ON THE CALL CAN CHIME IN AFTER DON. I'M
21 SORRY. EVERYBODY IS SITTING HERE, SO I CAN SEE
22 THEM.

23 MR. REED: THIS IS A TREMENDOUS IDEA WITH
24 SOLID COMMON SENSE. NATURALLY I WOULD THINK ANY
25 PATIENT ADVOCATE WOULD BE IN FAVOR OF CONCENTRATING

BARRISTERS' REPORTING SERVICE

1 THIS WEALTH OF TALENT AND OPPORTUNITY IN CALIFORNIA.

2 ON A COMPLETELY DIFFERENT SUBJECT, BUT

3 THIS IS THE ONLY TIME I HAVE TO BRING IT UP, WE ALL

4 KNOW ABOUT THE BREAKTHROUGH OR MAYBE A BREAKTHROUGH

5 ON SOMATIC CELL NUCLEAR TRANSFER. NOW, WE MAY HAVE

6 FORGOTTEN THAT WHEN PROPOSITION 71 WAS FIRST

7 DEVELOPED, ONE OF THE KEY REASONS FOR IT WAS TO

8 ADVANCE SOMATIC CELL NUCLEAR TRANSFER, WHICH IS

9 BEING DENIED SYSTEMATICALLY BY THE FEDERAL

10 GOVERNMENT. IN FACT, WE HAVE LANGUAGE IN THE BILL

11 ITSELF WHICH SAYS PREFERENCE WILL BE GIVEN TO

12 RESEARCH NOT FUNDED OR NOT LIKELY TO BE FUNDED BY

13 THE FEDERAL.

14 SO SCNT HAS ALWAYS BEEN VERY, VERY

15 DIFFICULT AND STILL IS. THERE'S STILL OBSTACLES IN

16 THE WAY, BUT I THINK IT HAS TREMENDOUS POTENTIAL.

17 I'D LIKE THERE TO BE CONSIDERATION GIVEN TO SOME WAY

18 TO ENCOURAGE SCNT FROM WHERE WE STAND BEFORE IT GETS

19 TOO LATE IN THE CYCLE. I THINK IT HAS THE POTENTIAL

20 TO BE A HOME RUN HIT. AND I THINK IF WE CAN

21 OVERCOME THE OBSTACLES, THAT WE CAN DO SOMETHING

22 FANTASTIC. SO I'D LIKE SCNT TO BE CONSIDERED IN

23 WHATEVER WAY IT CAN BE.

24 CHAIRMAN SHEEHY: WERE THERE OTHER BOARD

25 MEMBERS WHO HAD COMMENTS? ARE THERE ANY OTHER BOARD

BARRISTERS' REPORTING SERVICE

1 COMMENTS AT ALL? ANY OTHER PUBLIC COMMENT?

2 DR. LEWICKI: JOHN LEWICKI FROM ONCOMED.
3 WITH THE STRATEGIC PARTNER PROGRAM, WILL THE AWARDS
4 TO INDUSTRY, ARE THEY CONTEMPLATED TO ONCE AGAIN BE
5 IN THE FORM OF LOANS? IS THAT THE CURRENT PLAN?

6 MS. BAUM: I WOULD SUGGEST THAT IF IT'S A
7 NONPROFIT, IT WOULD BE A GRANT. AND IF IT'S A
8 FOR-PROFIT, IT WOULD BE A LOAN.

9 DR. LEWICKI: OKAY. AND WHAT ABOUT
10 POTENTIAL REPAYMENT TERMS FOR THE LOAN?

11 MS. BAUM: OUR REGULATIONS WOULD APPLY.

12 DR. LEWICKI: ALL RIGHT. I JUST WANTED TO
13 SPEAK OUT BECAUSE WE HAVE BEEN INTERACTING WITH
14 RESPECT TO THE DISEASE TEAM AWARDS, AND I JUST
15 WANTED TO SPEAK OUT FOR THE ALTERNATIVE RISK PREMIUM
16 REPAYMENTS BEING A FEATURE THAT'S VERY ATTRACTIVE TO
17 INDUSTRY AS OPPOSED TO WARRANTS, WHICH CAN, NOT
18 INFREQUENTLY, BE COMPLICATED AND NOT AS ATTRACTIVE
19 TO SMALLER PRIVATE COMPANIES.

20 SO IN THE CONTEXT OF THE LOANS, I JUST
21 WANTED TO ADVOCATE FOR THE ALTERNATIVE RISK PREMIUM
22 REPAYMENTS. I UNDERSTAND THAT THAT OPTION MAY BE
23 GOING AWAY IN THE FUTURE, AND I JUST WANTED TO
24 ADVOCATE FOR IT.

25 CHAIRMAN SHEEHY: IT'S NOT GOING TO

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1 DISAPPEAR INTO THIN AIR. I THINK WE'RE GOING TO
2 HAVE AN ANALYSIS. THERE WILL BE A DISCUSSION, AND
3 IF IT'S A PROGRAM THAT'S WORKING OUT, I THINK THE
4 BOARD WILL --

5 DR. LEWICKI: I JUST WANTED TO SAY FROM
6 OUR VANTAGE POINT WE FIND THAT TO BE A VERY
7 ATTRACTIVE OPTION.

8 CHAIRMAN SHEEHY: ANY OTHER COMMENTS FROM
9 ANY OTHER BOARD MEMBERS OR FROM THE PUBLIC? MEETING
10 IS ADJOURNED.

11 (THE MEETING WAS THEN CONCLUDED AT
12 02:54 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 SCIENCE SUBCOMMITTEE OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON OCTOBER 10, 2011, 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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