

VERBATIM PROCEEDINGS

CONNECTICUT STEM CELL RESEARCH ADVISORY COMMITTEE

COMMISSIONER DR. ROBERT GALVIN, CHAIRMAN

SEPTEMBER 16, 2008

CONNECTICUT ECONOMIC RESOURCE CENTER
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RE: CT STEM CELL RESEARCH ADVISORY COMMITTEE
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1 . . .Verbatim Proceedings of a meeting of
2 the Connecticut Stem Cell Research Advisory Committee held
3 on September 16, 2008 at 1:10 p.m. at the Connecticut
4 Economic Resource Center, 805 Brook Street, Rocky Hill,
5 Connecticut. . .

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7
8
9 CHAIRMAN DR. ROBERT GALVIN: I call to
10 order. Attorney Horn, do you need to record -- you have
11 recorded who is in attendance?

12 MS. MARIANNE HORN: I have and we do have a
13 quorum.

14 CHAIRMAN GALVIN: We do have a quorum and
15 on the phone is Amy, and Ann, and Treena, and Steve.
16 Okay.

17 Opening remarks, the only thing I have to
18 say is that we have negotiated with the Department of
19 Administrative Services and the Offices of Policy and
20 Management and we will be able to provide some
21 reimbursement to the case reviewers. That's going to vary
22 from about 800 or so dollars up to perhaps 3,000 dollars.
23 Warren will be busy working with the Division of
24 Administrative -- Department of Administrative Services

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1 because each of those individual case reviewers will need
2 a contract in order to be paid, but they will be paid.
3 Unfortunately, what I consider a minimal amount of money,
4 but at least it is enough to reimburse them for their time
5 and some other things. I don't know if Warren has
6 anything to say about --

7 MR. WARREN WOLLSCHLAGER: -- no, we
8 appreciate -- Marianne found the statutory site to allow
9 the Department to go forward and the Commissioner
10 personally interceded both with OPM and DAS as required by
11 the law to get their sign off. We're going to pay them on
12 a per grant review rather than a per diem because unlike
13 the NIH or all the other states we don't bring people
14 together for one or two days. So we're going to pay
15 people for a varying amount depending on from junior
16 investigator all the way up through core application. And
17 a minimal amount is a 100 dollars, maximum is 400 per
18 application. So we're excited.

19 CHAIRMAN GALVIN: Okay. The next item is
20 approval of the minutes of the 23 July 2008 meeting. There
21 is a draft of that document in front of most of us, and if
22 you've had a chance to review it previously, fine. If you
23 want to take a few minutes -- I'll give you a few minutes
24 to look through it now and see if there things that are of

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1 concern that need to be amended, changed, added or
2 subtracted.

3 DR. MILTON WALLACK: I move for their
4 acceptance.

5 MR. ROBERT MANDELKERN: Seconded.

6 CHAIRMAN GALVIN: All in favor. We're
7 voting on accepting the minutes of Wednesday, 23 July
8 2008. All in favor?

9 ALL VOICES: Aye.

10 CHAIRMAN GALVIN: Opposed? The motion is
11 carried and the minutes are accepted.

12 Our next item is No. 3, 2008 contract and
13 funding update, approval and status from CI and Chelsey.

14 MS. CHELSEY SARNECKY: Yes. So I have good
15 news, all of the contracts went out to the universities,
16 all but one, that's Evergen which we're going to be
17 talking about later on this afternoon. And the checks were
18 sent out and the universities are all set. So it's very
19 short, but good news.

20 MR. MANDELKERN: That's great.

21 MS. SARNECKY: Yes.

22 MR. MANDELKERN: Commissioner?

23 CHAIRMAN GALVIN: Yes.

24 MR. MANDELKERN: I would say that's a great

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1 successful effort and I commend Chelsey and CI for the
2 work. We're underway for 2008, full steam ahead to 2009.

3 MS. SARNECKY: Thank you.

4 CHAIRMAN GALVIN: Thank you. Item No. 4,
5 RFP approval, vote. I think, Marianne, are you going to
6 handle this item?

7 MS. HORN: Yes. And if you have the copy of
8 your RFP in front of you, this would be the one that on
9 the second line says, letter of intent, submission
10 deadline October 31, 2008. I can walk you through the
11 changes that were made from the original document.

12 CHAIRMAN GALVIN: Would you do that,
13 please?

14 MS. HORN: I will do that. The first
15 change is on what is essentially page two. We will have a
16 table of contents page, which is page one. We've slightly
17 modified the definition of escrow committee that would
18 comply with the legislative language that was passed this
19 year. It's really a technical correction.

20 The definition of IRC, Institutional Review
21 Committee, was deleted also reflecting the legislation. It
22 does not negate the requirement that an IRB, Institutional
23 Review Board, participate in a review of all of the
24 embryonic stem cell research or stem cell research as

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1 required by -- under federal law. But it's not
2 specifically set out in this. But the escrow is required
3 now under law and so we just made those definitions match
4 up.

5 Let's see. Under eligible applicants, still
6 on page two, we had a sentence in there that was somewhat
7 confusing. And it said that an eligible applicant had to
8 have their primary location in Connecticut. And that has
9 been deleted and what we replaced that with was a
10 requirement that the research must be conducted in
11 Connecticut except under extraordinary circumstances.
12 This will take away some of the questions that we had
13 about what a primary location was and as long as the
14 research is being conducted in Connecticut, as we
15 discussed last year in the grant review, if there is a
16 piece of machinery that is far too expensive and is
17 located in France that's not sensible to buy that piece of
18 machinery, that we would fund something like that. But
19 only under extraordinary circumstances does the money
20 leave Connecticut. We thought that was clerk and more in
21 line with the intent of the legislation.

22 So that new language appears over on page
23 three under who may submit, the third line down. So
24 except under extraordinary circumstances all research must

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1 be conducted in Connecticut.

2 Now feel free as I go through to bring up
3 any things that you feel like we haven't addressed or are
4 certainly questions about any of the decisions that were
5 made.

6 DR. WALLACK: If we have some substantive
7 questions on the overall approach should we hold that
8 until you finish because I think you're just reviewing
9 editorial comments for the most part.

10 MS. HORN: I am. Although when we get to
11 the actual discussion of the different types of grants and
12 the priorities I would certainly want people to weigh in
13 about whether what we have in there is still what the
14 Committee would like to have happen.

15 DR. WALLACK: Okay.

16 MS. HORN: Under when to submit on page
17 three there has been a change just eliminating the sending
18 of hard copies. It is to be all done with electronic
19 copies. The letter of intent is to be submitted by
20 October 31st at 4:30 and the proposals December 8, 2008.
21 We also added a requirement or a statement no additional
22 proposals or supplemental materials will be accepted after
23 the deadline because we did run into a significant amount
24 of that after the deadline last year.

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1 Over on page four just a minor change in
2 the first full paragraph here. We had originally the
3 advisory committee reserves the right to delay or decline
4 funding. And in the reading this in context we changed
5 the language to delay or rescind the funding rather than
6 decline funding. So since the approval had already been
7 given and needed to be rescinded if there was any change.

8 Now down into an area where I think Milt
9 might be talking about weighing in more substantively.
10 Under types of awards on the -- under the seed grants we
11 have set aside a total annual funding for seed grants,
12 grant awards will be at least 10 percent of the total
13 budget for the Connecticut Stem Cell Research grants
14 program. I just wanted to verify with the Committee that
15 that still is their will. Hearing no comments we'll move
16 on.

17 DR. GERALD FISHBONE: I have a question.
18 What defines a seed grant?

19 MS. HORN: The seed grant is defined below
20 that.

21 DR. FISHBONE: Below that?

22 MS. HORN: Yes.

23 DR. FISHBONE: I see.

24 MS. HORN: Under No. 1 a seed grant

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1 generally goes to junior investigators. And so the
2 funding may be up to 200,000 and expended over two years.
3 And the applications are limited to five pages. Any
4 concerns, questions? Okay.

5 Established awards, the award may be up to
6 500,000 and extended over four years. And the grant
7 application is limited to ten pages. Under group project
8 awards the project award may be up to two million, up to
9 four years, and fifty pages. And core facility awards the
10 funding may be up to two and a half million and may be
11 budgeted for up to four years and the applications are
12 limited to 50 pages.

13 MS. LISA NEWTON: Good afternoon.

14 MS. HORN: Yes, good afternoon.

15 MS. NEWTON: Lisa, Lisa Newton.

16 MS. HORN: Oh, hello Lisa. Marianne Horn,
17 we're just going through the RFP. Lisa sits on the Ethics
18 and Law subcommittee.

19 DR. WALLACK: On the core facilities
20 awards, we've had discussions in the past relative to the
21 necessity of going forward with core grants on an on-going
22 basis. And I think some of the premise having to do with
23 that was the fact that once you've established your cores
24 do we have to establish new cores. I understand the

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1 wording here says new and/or enhanced cores or already
2 existing cores. But in the last go around we specifically
3 left in cores because we realized there were certain
4 deficiencies that the cores were experiencing relative to
5 our lack of ability in the first go around, the first 20
6 million to fund them fully. And so we went forward and we
7 funded them in a more substantive way.

8 My sense though is that those cores that
9 are already in existence through this last round are
10 probably at a point where they may not be coming back to
11 us for enhanced funding. We're only dealing with 10
12 million dollars now. We had a very difficult time in April
13 going through all the applications relative to who we
14 funded or not. And there was some very good research that
15 either had to be cut or eliminated.

16 I guess you can sense where I'm going with
17 this and that is do we, at least for this coming year,
18 since we funded the cores for two consecutive years do we
19 say we don't feel we need to do that and we'd rather use
20 the entire sum of money to fund just the best research.
21 So that's what I'd like to put on the table with my
22 inclination or my prejudice being maybe towards holding
23 back on core funding at this point.

24 MS. HORN: Comments from the group on this,

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1 on Milt's comment?

2 MR. WOLLSCHLAGER: If I may comment just a
3 point of clarification, we did fund a new core last year.

4 DR. WALLACK: Okay.

5 MR. WOLLSCHLAGER: So it wasn't just
6 continuation funding for the two existing cores, we did
7 agree to fund the third core which was new at that time
8 and has yet to receive any funding. So that's just still
9 out there.

10 DR. WALLACK: The substance of what I said
11 is still, I think, fairly accurate.

12 MR. WOLLSCHLAGER: Well, I just want to
13 point out that absent language that allowed for new core
14 applicants we would not have been able to fund that
15 particular proposal.

16 DR. WALLACK: I understand.

17 MR. MANDELKERN: Marianne? If I recollect
18 correctly in this last round of funding we did extend one
19 of the cores we had previously funded. However the second
20 core was minimally -- was very little funded and I think
21 the opportunity should be left in there for them to
22 submit. We don't know what kind of peer review they would
23 get or how the Advisory would respond, Milt. But I think
24 we shouldn't foreclose the possibility of the one that we

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1 established the first time around, which we minimally
2 advanced second time.

3 There is also, as Warren pointed out, we
4 did fund a new core this last round.

5 DR. WALLACK: No, they were proposed.

6 MR. MANDELKERN: Yes, we did. No, no, it
7 was awarded, Milt. It hasn't been granted.

8 DR. WALLACK: Right.

9 MR. MANDELKERN: Because of a pre-
10 condition.

11 DR. WALLACK: Right.

12 MR. MANDELKERN: However on April 1st it
13 was awarded and the revised budget was also approved. I'm
14 not arguing one way or another. I'm just trying to set the
15 record straight. The grant was awarded on April 1. They
16 revised the budget because the original grant had been cut
17 in half and we approved the revised budget. Nothing has
18 been done contractually and no money has gone out.

19 So my point would be to finish to leave the
20 cores there as a possibility not to limit the scientific
21 research chances in Connecticut. That's all.

22 CHAIRMAN GALVIN: I think that's a
23 reasonable statement.

24 MS. HORN: Any other comments? I think it

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1 makes sense maybe to leave it in and we don't -- there is
2 no necessity to fund any grant, any core grant if there
3 either aren't grants or there are not ones that are -- the
4 Committee wants to fund. But it maybe a little premature
5 to take it out this year.

6 DR. WALLACK: I fully anticipated that we
7 would continue to leave it in. So I have no problem with
8 that. I have no reservation, however, about the need to
9 at least have the discussion and to speak amongst
10 ourselves about the fact that what we have done with the
11 cores. And while I totally agree with the need for strong
12 cores, but the flip side of the discussion that I put on
13 the table has to do also with the fact that we have to
14 recognize that with only 10 million dollars each go
15 around, and with the kinds of research that we have not
16 unfortunately been to fund, that we should keep this all
17 in mind as we go through the decision making process.
18 And if -- so I really think it's important to highlight
19 that.

20 MS. HORN: Very good.

21 CHAIRMAN GALVIN: Please continue.

22 MS. HORN: Thank you. Over on page six, we
23 have our -- the selection criteria. And I just wanted to
24 verify that we're still okay with those.

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1 MR. MANDELKERN: Page five, Marianne.

2 MS. HORN: Page five on yours? Okay. For
3 whatever reason it's page six on mine. Sometimes they
4 print out a little bit differently. So selection
5 criteria, any changes to that? We're ready to carry on
6 with that for another year?

7 Okay.

8 DR. FISHBONE: Could I just ask one
9 question about the cores? Could I ask a question about
10 the cores? What was our original plan? We gave them money
11 to get established. I'm assuming they would use that
12 money year after year. What would happen subsequently like
13 in the third and fourth and fifth years to the cores that
14 we supported? I mean did we have a concept of will the
15 universities pick it up or would, you know, would they
16 need to keep coming back for more funding year after year?

17

18 MS. HORN: I don't really know what we had
19 thought about that. Maybe some of the scientists can tell
20 us how they -- how a core continues to function without
21 specifically targeted core funding in subsequent years.

22 DR. AMY WAGERS: Well, one way that the
23 cores often supplement not having enough funding is by
24 charging the user to make use of the core. It comes under

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1 user fees. And so it keeps the cost of running the core by
2 charging users for their -- and most cores -- (inaudible)
3 -- they have to operate at a (inaudible) then they would
4 start charging users who would pay -- out of their grant
5 money. And if the users decided after a while to not use
6 the core then the core is not viable then it would close.

7

8 CHAIRMAN GALVIN: Okay, Amy, if you and the
9 other ladies who are phone can identify themselves I think
10 it would make a little easier for our transcriptions.
11 They know that the one with the deep voice is Steve.

12 DR. WAGERS: Sorry about that, yes, this is
13 Amy.

14 CHAIRMAN GALVIN: Okay.

15 MS. HORN: Thank you, Amy. Okay, thank
16 you. Does that address your question?

17 DR. FISHBONE: Yes, it does.

18 MS. HORN: Okay.

19 MR. MANDELKERN: I would also, Gerry, if
20 you recall we were very careful when the extension of the
21 original core came up this time. We didn't accept their
22 progress. We made them both come back and report to us
23 before we approved the release of additional funds. We had
24 them back to really examine scrupulously what was going

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1 on. So I think we've paid close attention and we'll see
2 what the next RFP brings, but I think the important thing
3 is to get the -- we did pay scrupulous attention to the
4 project of the original cores by calling them back for
5 progress reports, for careful review before we renewed the
6 funds for the second year. And I think the important
7 point now is to get the RFP out because it won't be going
8 out till late and it won't be filed until the last month
9 of the year. So I think we have to move forward with all
10 of those issues.

11 CHAIRMAN GALVIN: Okay, please, continue.

12 MS. HORN: Okay. So no changes to
13 selection criteria. Under proposal review we added a
14 sentence that indicates that an applicant may send to
15 Connecticut Innovations the name of any reviewers with
16 whom there is a conflict of interest and who should not be
17 considered as reviewers. On the flip side, any reviewer
18 who has a conflict with a grant notifies us that they have
19 a conflict. This is just the other side of that.

20 We have a couple of minor changes, nothing
21 significant. Over onto the page seven, just an addition of
22 having escrow approval for the research project prior to
23 the release of funds. We had that in several other places
24 and we just wanted to make clear that that was a

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1 requirement before any of the funding is released and
2 we'll be addressing that situation in its form as we get
3 through the agenda.

4 Let's see. The next paragraph starting in
5 the funding period begins on the effective date that we
6 clarified some of the language in there over funding,
7 carry over funding. There was a little bit of fuzzy
8 language in the initial RFP and that has been clarified
9 and made consistent with the language in the contract as
10 well, the assistance agreement.

11 The proposal, again, at the bottom of page
12 seven has to be electronic. At the top of page eight, we
13 added a sentence that says proposals that don't follow the
14 prescribed format or are incomplete when they're submitted
15 or otherwise do not conform to the requirements of these
16 proposal instructions may be rejected as ineligible for
17 consideration. Last year we got some grants that didn't --
18 the last phrase is the one that we added, that do not
19 otherwise conform to the requirements. We did get a
20 proposal that was -- it followed the prescribed format. It
21 was not incomplete, but it didn't conform to the
22 equipments. We sometimes get grants that are clearly not
23 appropriate for the program or, for example, the budget
24 was five times what was required. So we needed to make

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1 sure that we had a grounds for just doing a technical
2 review of that and not bothering the peer review and the
3 Advisory Committee with the review of those.

4 Over onto page nine, there was a definition
5 here, this is -- we are talking about intellectual
6 property here. There was a definition that was added in
7 the first RFP of invention. And there is a refined and I
8 am told a much more industry consistent definition in the
9 assistant's agreement for invention. And so we took the
10 invention definition out of the RFP. It really doesn't
11 need to be in there and it was confusing.

12 You can tell not huge changes in here.
13 Over on page ten, travel we added a phrase that 5,000
14 dollars a year is available to travel to conferences to
15 present findings or to further the research. It was
16 relayed to us that only going to conferences to present
17 findings might be a little restrictive for scientists who
18 need to meet and hear what else is going on in the field.
19 It's a wonderful way of exchanging and advancing the
20 science.

21 Over on page 12 we added a sentence both to
22 changes -- adherence to original budget estimates and
23 changes in personnel. I think this was Ann Kiessling
24 suggested this that we'd like to have a description of the

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1 impact of these changes on the conduct of the research. It
2 wasn't clear to us last year, a couple of times, what
3 impact this might have.

4 This language also clarifies the
5 reallocation request thresholds. We had some confusion
6 about whether it was in the aggregate or only a single
7 event.

8 And project reports, there was quite a bit of
9 discussion last time about these project reports not being
10 detailed enough, not containing enough information for the
11 Committee to make an assessment about how they were doing.
12 We added a bullet, added to the last bullet that we wanted
13 detailed summary in lay language on a form provided by
14 Connecticut Innovations. And the form from Connecticut
15 Innovations will contain the detail. Amy Wagers gave us
16 some wonderful language for that and we'll incorporate
17 that into the form that will provide the scientists with
18 much more direction about what we're looking for in those
19 lay summaries.

20 DR. WALLACK: Are there instances where,
21 and I'm addressing this really to the researchers I think,
22 that there is more than a 12 month review? Are there
23 instances where there is say a six month review at all? I
24 mean is that something that's -- that happens?

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1 DR. WAGERS: I'm not quite sure I
2 understood the question.

3 DR. WALLACK: Amy, instead of reviewing
4 only the activities of the year, the 12 month -- on a 12
5 month basis in your experience from the grants that you've
6 gotten is there ever a request to have your review say on
7 a six month basis as opposed to a 12 month basis?

8 DR. WAGERS: Yes, I have had that request. I think --
9 and you're talking about an experiment or because we find
10 something and there is a potential problem?

11 DR. WALLACK: Right, exactly, the latter.

12 DR. WAGERS: Okay, yes. It probably would
13 put too much burden on the Committee reviewing, but a
14 progress report, but I think it's a complete reasonable
15 thing to request in the instance where we have some
16 concerns and we want to get feedback on how they're doing
17 right away.

18 DR. WALLACK: So could -- would we want to
19 consider that there might also be the possibility that we
20 would ask for a more frequent review?

21 MS. HORN: Yes, I believe we did that in
22 the first year. There were some large grants that I
23 believe reported back after six months. And those reports
24 were made available to the Committee members. And that

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1 could be written in as part of the grant approval or part
2 of the contracting process. It's certainly possible.

3 MR. MANDELKERN: Milt, specifically when
4 the Nychiam grant came up for extension we felt that there
5 was a minimum amount of progress. And I believe that we
6 requested a six month report rather than a 12 month on a
7 grant that we reviewed and we found wanting. Now whether
8 that should go in the RFP or not I don't know, but we did
9 it.

10 DR. WALLACK: That's what's prompting my
11 question, Bob.

12 MS. HORN: Okay.

13 MR. MANDELKERN: Yes. But we did to it in
14 reality.

15 DR. WALLACK: I'm just wondering, I'm not
16 saying that we should put in here that they would
17 automatically be a six month review. But maybe if we could
18 find a way to put a sentence in that would indicate that
19 if the Committee felt it necessary we might ask for a more
20 frequent review. That way, at least, there is no surprises
21 to the researchers if we did that because of the
22 experience that we had, Bob.

23 CHAIRMAN GALVIN: Yes, I think that's
24 inherent in the power of this Committee.

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1 DR. WALLACK: Okay.

2 CHAIRMAN GALVIN: That should we decide to
3 review something at the end of a six month period and are
4 not unhappy, and not happy with it we might want to review
5 it in 60 days or 90 days. And subsequently for every 90
6 days until we were certain it was on track. But I don't
7 think we need to -- I don't think we need to spell that
8 out. I think that's inherent.

9 We'll bring something, up which I really
10 don't like to, but I was at a board meeting at the
11 University of Connecticut Medical School yesterday and a
12 topic labeled nepotism came up. And apparently the state
13 auditors had discovered that on four grants out there the
14 principal investigator had been supervising a spouse,
15 which was termed nepotism. And apparently with the NIH
16 there is a way of doing this so that you don't have direct
17 Dr. A is directly supervising Dr. B. At the medical
18 school it was though to be all right if the Departmental
19 Chairman took over the direct supervision of the spouse or
20 blood relative, whoever that may be. I think in most cases
21 and I don't think that question has ever occurred to us
22 that Dr. A may be supervising Dr. B. And for all we know
23 maybe they don't have the same last names and that we've -
24 - don't even realize that Dr. X is Dr. Y's spouse.

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1 So -- and I guess there is a -- I don't
2 know if some of our folks who are more used to dealing
3 with the NIH have ever encountered this, but the matter
4 was raised, which I thought was -- I was dismayed at, but
5 it is -- there is some pertinence to it.

6 Amy or Ann, do you have any experience with
7 this? Has that ever come up in your background?

8 DR. WAGERS: Yes, this is Amy.

9 CHAIRMAN GALVIN: Yes.

10 DR. WAGERS: I worked in a lab who ran --
11 so I guess in experience it hasn't come up. I mean it's
12 not actually -- her style is to work together and find
13 there is nothing uncommon. Are you suggesting that we
14 need to include language in our RFP about this?

15 CHAIRMAN GALVIN: I, as you know, am not a
16 person who is inclined to be nit picky, but since the
17 state auditors raised the question I wondered if we should
18 we have at least a -- the response from the university was
19 we do it the way NIH says to do it. And the response back
20 from the auditors appeared to be that it was somehow
21 unseemly. And I don't know what you're supposed to do if
22 you're -- maybe if you fall in love while you're doing the
23 grant you have to throw your intended out of the
24 department or whatever. I really don't know. I just

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1 wonder if they're going to raise that question.

2 DR. WAGERS: There are many husband and
3 wife research teams. Yes, that's very, very common.
4 They're frequently so successful that places like the
5 University of Pittsburgh in Pittsburg they specifically
6 recruiter husband and wife teams. They find them to be
7 stable and very productive. I have never sat on a study
8 section where anybody questioned the fact that whoever was
9 the PI was supervising whoever was their spouse.

10 CHAIRMAN GALVIN: Okay. I think we have to
11 --

12 DR. WAGERS: -- frequently spouses, one of
13 them will be the PI and the other will be say a co-PI.

14 CHAIRMAN GALVIN: Yes,

15 DR. WAGERS: And then the alternate will go
16 the different grant on a similar topic and they'll both
17 have their own grants, and they'll each be on their each
18 other's grants. I've never heard the word nepotism come
19 up at study sessions.

20 CHAIRMAN GALVIN: I thought it was unusual.
21 Shouldn't we alternate saying wife and husband instead of
22 husband and wife just to be politically correct? That
23 does not require an answer. I think we should --

24 DR. WAGERS: -- you have to be careful

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1 because it could be husband and husband.

2 CHAIRMAN GALVIN: Or wife and wife, and
3 significant other. Yes, I think we should just move on,
4 but the question was raised someplace.

5 MS. NEWTON: Can I go back for ten seconds
6 and maybe save some time? One problem you were dealing
7 with ten seconds ago and I was physically trying out some
8 alternate wording. How about asking people to report more
9 often, why don't you just put that sentence, principal
10 investigators are required to document technical progress
11 reports annually or at such intervals as the Commission
12 may request.

13 MS. HORN: Lisa, I'm sorry, to interfere,
14 it's Marianne. We're just having the Advisory Committee
15 weighing in here and we'd love to have your comments when
16 we get to the Evergen and the escrow, and the report out
17 of the ethics and law. But I'm sorry, we're just
18 confining this discussion to the Advisory Committee right
19 now.

20 MS. NEWTON: Okay, can I hang up? When are
21 you going to take on the Evergen?

22 MS. HORN: Let's see. We are almost through
23 the RFP and it's up --

24 CHAIRMAN GALVIN: -- why don't we take that

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1 as soon as we finish the RFP?

2 MS. HORN: We could do that.

3 CHAIRMAN GALVIN: So that this person
4 doesn't have to hang on the phone.

5 MS. HORN: Right.

6 CHAIRMAN GALVIN: And listen to us.

7 MS. NEWTON: I'm going to keep quiet.

8 CHAIRMAN GALVIN: Well, very few people
9 here keep quiet, but we have to stay within the boundaries
10 of the Robertson's Orders.

11 MS. HORN: I have to be the bad guy here,
12 I'm sorry. Paul had a comment.

13 DR. PAUL PESCATELLO: Two comments, the
14 first on the nepotism I would be really surprised, I mean
15 if I understand it correctly, if a -- if one spouse is
16 supervising another spouse I would be surprised if that
17 falls within the requirement of high ethical standards. I
18 mean I can't imagine that -- as productive as those teams
19 might be in practice I would -- I wouldn't want to have to
20 defend a spouse supervising a spouse that that was okay.

21 CHAIRMAN GALVIN: I think that since Amy
22 and Ann have had experience with this and this is what
23 people do and it's the accepted way of doing things that
24 we shouldn't make an issue about it. If the auditors want

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1 to make an issue about it they can -- when the dust has
2 cleared they said, well they guessed it was all right, but
3 it was -- I think the word was unseemly. I'm not sure who
4 came up with the word, but I mean I don't know what we're
5 going to do. If we've got two partners who came here
6 perhaps from Asia and then are we going to send one back
7 home because the other one is the principal in the grant
8 or have one of them go to Oregon and the other one stay
9 here. That gets to be -- I just raised the issue so we
10 have an answer that we could say, look we discussed this.
11 Just don't bother us anymore with it.

12 MS. HORN: Yes, they'd certainly have to
13 comply with any requirements of their institution.

14 CHAIRMAN GALVIN: If they're behaving
15 unethically? I mean what are you going to do? We want to
16 make sure that nobody gets divorced while they're in the
17 middle of this either. So they don't get mad at each other
18 and sabotage -- I mean just as long as we considered it, I
19 think we're okay.

20 MS. HORN: Okay, very good.

21 DR. PESCATELLO: There is a conflict of
22 interest overlays that somebody --

23 MS. HORN: -- in a position of power.

24 DR. PESCATELLO: Is watching, correct?

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1 MS. HORN: Yes. I think --

2 DR. PESCATELLO: -- and this wouldn't fall
3 under that conflict or anything?

4 CHAIRMAN GALVIN: No.

5 DR. PESCATELLO: So if I was the principal
6 investigator supervising my son or daughter would that be
7 allowed?

8 MR. MANDELKERN: A little louder, please.

9 DR. PESCATELLO: If I were supervising my
10 son or daughter would that be okay? Would that be
11 allowed? I mean I don't think it falls under just a common
12 sense -- I mean nepotism is nepotism, it's like one of the
13 oldest things you want to avoid, I mean.

14 DR. ANN KIESSLING: I have a question just
15 in terms of -- this is Ann Kiessling. I have a question
16 just in terms of general, the state granting contracts
17 does the state not grant contracts to people who employ
18 their spouses?

19 CHAIRMAN GALVIN: I don't think that's ever
20 been an issue with a contract. We have several spousal
21 pairs in my department and no one has said anything
22 officially about it. Somebody who got disciplined made a
23 complaint about it that it wasn't fair to have X inspect
24 him and Y, you know, discipline him. But --

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1 DR. PESCATELLO: -- I'm not saying that
2 they should be banned, just that they're -- I would assume
3 there would be some kind of supervisory process in place
4 so that you don't end up with --

5 MR. WOLLSCHLAGER: -- can I say just this?
6 Our peer reviewers, the Stoltz, Mildrag and his wife work
7 together all the time. And I don't know if it was Ann or
8 Amy that was describing a process where the one is the PI
9 and then the other is the BI and they sort of go back and
10 forth. I think that's what they do over there. So I'd be
11 happy to follow up with them and see how they do it.

12 CHAIRMAN GALVIN: I think as long as we
13 said we've looked at it. I mean we could get down and say,
14 okay, if it's a couple whether they're husband and wife,
15 or husband and husband or whatever, that's okay, but
16 father and son or -- and then what about cousins and
17 uncles and aunts? I mean we could take it down to what
18 sort of blood lineage do you have to have before you're a
19 nepot? Is that what you call somebody who engages in
20 nepotism?

21 MS. HORN: A nepot.

22 CHAIRMAN GALVIN: A nepot. Okay.

23 MS. HORN: I think the concern is with the
24 fairness of the process.

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1 CHAIRMAN GALVIN: Yes.

2 MS. HORN: In the state that you're hiring
3 somebody because they're your spouse or they're your son
4 or daughter. And if it's a fair and transparent and
5 equitable process then --

6 CHAIRMAN GALVIN: -- I think we're okay as
7 long as we're aware. Yes, Bob.

8 MR. MANDELKERN: I would think that it's
9 laudatory of the auditors to be so scrupulous and to have
10 called this to the attention, but I think that our job is
11 to evaluate the quality of the work not the nature of the
12 people who perform the work. They can be significant
13 others, insignificant others. When they bring in the
14 progress report it has to stand on its own feet regardless
15 of who the supervisor is and who the researcher is.

16 CHAIRMAN GALVIN: Well, I agree with you.
17 We could get into the situation saying that Smith
18 supervised Jones and they're not married, but they live
19 together. Or they used to be married but they're not. I
20 mean it's -- endless permutations.

21 MR. MANDELKERN: I think we should --

22 CHAIRMAN GALVIN: -- yes.

23 MS. HORN: If we can just quickly go
24 through the last couple of things. They're very minor

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1 things and really --

2 DR. PESCATELLO: -- this is a second point
3 unrelated to the nepotism, just on the issue of more
4 periodic reviews, because I just want to -- we can talk
5 about it now or later on the strategic planning report
6 because we did talk about it at the strategic planning
7 committee meeting about having, you know, teams come in
8 and explain their research to this Committee on a regular
9 basis so that it's almost every meeting of this Committee
10 we have some kind of update, some kind of update and
11 learning process about the research that's going on.

12 MS. HORN: That's great. Okay. We're on
13 page --

14 DR. WALLACK: -- just one other thing. I
15 know Lisa Fenton can't comment.

16 MS. HORN: Newton, yes.

17 DR. WALLACK: Right. I might capture the
18 fact that the essence of what -- the essence of what I was
19 trying to articulate, not as well as Lisa, was that extra
20 few words that would indicate the opportunity -- and I
21 know Bob has rightly said that it's inherent in our
22 process, it just allows us to not spring any surprises on
23 the researchers and it also allows us to go back and do
24 what Paul indicated bring them forward for a monthly

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1 update on various, you know, at various times. If you
2 guys don't want to go with this that's fine, but I just
3 thought that it exhausts any discussion that I, at least,
4 would have on that point. But it does clarify my point.

5 CHAIRMAN GALVIN: I appreciate your
6 statement though. I'm just afraid that the more of these
7 qualifiers you build in, the more opportunity it gives
8 somebody to say I didn't quite -- I don't quite fit in
9 that category, and I would rather leave it broad enough so
10 that anyone of the members of the Board itself could say,
11 we're not comfortable here. We want to see if -- we want
12 to see you and then we're going to see you every 60 days
13 or whatever.

14 The other thing is I'm always afraid that
15 somebody will -- when you put some extra words in there
16 will use that to somehow get around you or say that well
17 you didn't -- you didn't tell me that right off the bat
18 when I was going to get the grant that you might call me
19 in. So you can't call me in or because it says -- the
20 wording -- whereas if we keep it constitutionally vague
21 then -- I don't mean vague, I mean so that we have the
22 ability to say, look, we're going to review Paul
23 Pescatello every six months, Walt Wallack every four
24 months, Gerry Fishbone every other month. I'd rather it

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1 see it open ended. But I can live with the other if that's
2 what you want.

3 DR. WALLACK: If you can live with both I
4 would feel that I would like to see it in only because to
5 me it would -- if I'm the researcher and it just says 12
6 months I can see them saying to me, I was only aware of
7 the fact that I may be brought in every 12 months. Now,
8 you're telling me I'm going to be brought in every six
9 months or seven months. I mean, Bob, it's not -- it's not
10 going to change the configuration of what we're doing.
11 It's --

12 CHAIRMAN GALVIN: -- we'll let Marianne put
13 some wording in there that says, more frequently as --

14 DR. PESCATELLO: -- I was going to say that
15 would lead up to the lawyers because I think that's a good
16 point -- if you start adding details one place then people
17 -- if you don't do it other places then people will --

18 CHAIRMAN GALVIN: -- yes. That's the name
19 of the game.

20 DR. PESCATELLO: You've been hanging around
21 with a lot of lawyers.

22 CHAIRMAN GALVIN: Yes.

23 DR. FISHBONE: The only problem I have is
24 that I think it probably takes a year for, especially when

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1 people are starting from scratch. We know in the first two
2 rounds it took three to four months for people to even
3 start their work, get all the equipment.

4 DR. PESCATELLO: Yes.

5 DR. FISHBONE: And, you know, I think you
6 have to give them an opportunity to show what they can do
7 at the end of that year. And what we have done with
8 several of them is at the end of the year when we reviewed
9 them and the progress wasn't satisfactory I think we said
10 to one or two we want to hear from you in three or six
11 months. But you have to give a reasonable length of time
12 to show whether they can do the work or not.

13 CHAIRMAN GALVIN: Yes, I agree and --
14 unless you thought something had gone very seriously wrong
15 or somebody from the institution said, you know, this guy
16 is just sitting up there reading and not getting anything
17 done. I mean it does really take someone about three or
18 four months just to get up to the starting line. Okay.
19 Yes, Bob.

20 MR. MANDELKERN: I would agree with Gerry
21 because the 2008 money has only reached researchers in the
22 last trimester. So if they get started by 2009 it would be
23 good. So I think --

24 CHAIRMAN GALVIN: -- that's fine.

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1 MR. MANDELKERN: There is room to -- when
2 the progress report comes in to make any demands we want.
3 I think the flexibility is all on us.

4 CHAIRMAN GALVIN: And I think what Paul is
5 trying to express is we want to say we may look at your
6 more frequently than at yearly levels. We will look at
7 your work as needed and with a frequency to be determined
8 by circumstances. And I think it would be unusual, but
9 unless we got word that somebody was -- had gotten a grant
10 for one thing and was off in the wrong direction or wasn't
11 even beginning, at six or seven months wasn't even
12 beginning to get into motion. Okay.

13 MS. HORN: The last three comments, on page
14 12 we had a statement that failure to submit required
15 reports could lead to denial or deferral of funding. We
16 added in or the submission of incomplete or inadequate
17 reports which was language that we didn't have in there
18 for last year and wished we had.

19 Over on the last page we had just a
20 correction to the documents as public records making clear
21 that all documents submitted to the grants program are
22 subject to being public records and the FOI not just
23 documents on funded proposals.

24 CHAIRMAN GALVIN: Say that again, I missed

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1 that, I'm sorry.

2 MS. HORN: Sure. We had the original
3 language we had was that all documents -- that documents
4 on funded programs that were submitted to the stem cell
5 program were subject to freedom of information and were
6 public records. That's not how the law reads. It's all
7 documents that are submitted to the program whether the
8 grant is funded or not. So we wanted to clarify that
9 anything you send us could be potentially a public record.

10

11 CHAIRMAN GALVIN: That's true. Gerry.

12 DR. FISHBONE: What about the grants from
13 industry where some of the material that they're
14 submitting to us may be privileged?

15 MS. HORN: Yes, and we highlighted that. It
16 is proprietary and privileged information can be indicated
17 as such. And we've highlighted that, those individual
18 words and paragraphs should be marked in bold because I've
19 spent way too many hours going through the grants trying
20 to figure out what pages three through 12 is all
21 proprietary means. So we've got that covered as well.
22 And that paragraph on documents is public records goes
23 through that, the process.

24 And that is it for us. There was a typo

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1 that Gerry picked up on page 15 that we'll correct.

2 CHAIRMAN GALVIN: Okay.

3 MS. HORN: Any other comments?

4 CHAIRMAN GALVIN: Dr. Wallack?

5 DR. WALLACK: Going back to page two, which
6 is the first page, in the first paragraph I know that we
7 had a rather extensive conversation two and a half years
8 ago and again last year that led us to the wording to fund
9 the best stem cell research proposals that Connecticut
10 scientists can offer. I'm just wondering, put it out there
11 just for a limited conversation, but at least know we've
12 touched on it by doing this, of whether or not at this
13 time we're ready to say something like the following.
14 That where it says research proposals that Connecticut
15 scientists can offer. The next sentence, perhaps could be,
16 we, in addition, encourage research that can lead to
17 translational clinical applications.

18 So for the -- if we did that the first time
19 in our process we'd begin to touch on -- and we're not
20 saying that we're -- that that's going to be the criteria.

21 But we put out there, at least, the -- and I think the
22 timeliness of this is that I would anticipate that we're
23 probably, as time goes on, if you judge by what's going on
24 up the street in Boston and so forth with reprogramming

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1 and so on, that we're going to see a swing to that, in
2 that direction anyway. So that -- and it would just be
3 creating an additional emphasis that we so far have not
4 touched on. So, again, the wording that I would propose
5 in the place that I proposed it would be that we, in
6 addition, encourage research that could lead to
7 translational clinical application.

8 DR. FISHBONE: This is in the overview?

9 DR. WALLACK: It's --

10 CHAIRMAN GALVIN: -- proposal instructions,
11 first sentence on page -- indexes two. We're right up here
12 at the top, Paul.

13 DR. WALLACK: The second sentence would be
14 what I said.

15 CHAIRMAN GALVIN: I don't have any problem
16 with that. Does anybody else?

17 MR. WOLLSCHLAGER: Is it going to be one of
18 the factors? I know you said no, but --

19 DR. WALLACK: -- no. I think that all this
20 is trying to do is for the first time begin to highlight
21 something that we've not touched on. And I think that at
22 this point, unlike two and a half, three years ago it's
23 appropriate to do it.

24 CHAIRMAN GALVIN: Okay. I think that this

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1 is certainly a worthwhile addition. I think at some time
2 in the future, owing to the fact that we have 10 million
3 dollars and we want to direct it in the appropriate --
4 into the appropriate areas, we may want to do some
5 considerable talking among ourselves about are we going to
6 start -- still be funding basic research and translational
7 research at the same time. I don't have to tell you that.

8 But are we going to concentrate on say
9 something like, you know, we've got several balls rolling
10 here now in year five or six where are we going with this?

11 Are we going to direct it towards cancer cells, which is
12 the cover story on The Economist this week, or last week.
13 Or are we going to still do fundamental primary research?

14 And I think this opens the door to that, but also will
15 lead at some time to a more -- particularly when we have
16 some of our senior scientists present at the table,
17 leading us into a more defined discussing about where are
18 we going over the next five to six years. Yes, Paul.

19 DR. PESCATELLO: I don't think it does any
20 harm, but I think that already it says the best stem cell
21 research Connecticut -- I mean that includes everything.

22 MR. MANDELKERN: Dr. Galvin.

23 DR. PESCATELLO: It gets to your earlier
24 point when you start adding -- if you sort of enter these

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1 caveats then it begs the question about the things you
2 don't say and I guess I would still say that, you know, in
3 my sense of stem cell research, you know, unfortunately in
4 a way is that it's still at a basic research level. I
5 mean as much as we want translational you can't force it.

6 It -- I mean --

7 CHAIRMAN GALVIN: -- let Paul finish. Well,
8 you know, and I can certainly -- I can certainly
9 understand your point. I think this does, you know, it
10 does provide a statement which is inherent and the best
11 research is the best research. Somewhere along the line
12 we've got to sit down and figure out, you know, which end
13 are -- are we going to be funding basic research or are we
14 going to look more for applied translational and applied
15 research. That's a very big question that we couldn't
16 decide here in an afternoon or maybe in a couple of
17 afternoons. But, you know, we really need Amy and Ann and
18 Treena and the people who are really down in the
19 scientific trenches, so to speak, to -- so we can make an
20 informed decision or not make a decision and just use that
21 particular, that particular generic comment.

22 I personally don't have any difficulty with
23 adding a sentence about translational, which would, in a
24 way, may serve the purpose of saying maybe we're not

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1 always going to be doing basic research. I think that
2 stakes to a little piece of territory, but then you know
3 maybe in a couple of years we're going to sit down and say
4 we want to find somebody who has got a really promising
5 project for cancer cells or kinds of cancer or not. But I
6 think this kind of opens the door to a broader discussion
7 and I have no problem including that. Go
8 ahead, Bob.

9 MR. MANDELKERN: Thank you, Commissioner. I
10 think I would support Paul's point that translational
11 research is included in the best research because I think
12 if you put a comma translational research then you can get
13 easily research with IPS cells, research with basic
14 embryonic, you know. If you put in qualifiers I think we
15 lose our ability to accept broad translational and
16 everything. I would think the less you add to it the
17 better it stands that we fund the best research including
18 all research, that's inherent in the best. So I would go
19 without the addition.

20 DR. WAGERS: This is Amy Wagers. If I could
21 make a comment perhaps we could just say that we're
22 funding the best basic and translational research. And
23 let it -- and it brings that idea of translation in
24 without putting a particular emphasis on it over basic.

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1 DR. WALLACK: I think Amy's idea is --
2 CHAIRMAN GALVIN: -- I'm good with that.
3 DR. WALLACK: Is better than mine.
4 CHAIRMAN GALVIN: I'm good with that.
5 DR. WALLACK: I agree.
6 CHAIRMAN GALVIN: Okay. Anything else?
7 MS. HORN: I am finished.
8 CHAIRMAN GALVIN: The next item is --
9 MS. HORN: -- thank you.
10 CHAIRMAN GALVIN: Are we going to go to
11 Evergen?
12 MS. HORN: Yes, we have to vote on -- there
13 has to be a motion to accept it with that one --
14 CHAIRMAN GALVIN: -- okay, what's the -
15 what are we accepting?
16 MS. HORN: We are -- the --
17 CHAIRMAN GALVIN: -- because we've got
18 folks on the phone here who can't see our wonderful faces.
19
20 MS. HORN: Right. We are needing a motion
21 to accept the RFP as amended as I've just described with
22 the additional language that was just proposed by Amy
23 Wagers.
24 CHAIRMAN GALVIN: And that's pages two

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1 through 16.

2 MS. HORN: Correct.

3 CHAIRMAN GALVIN: Okay.

4 DR. STEPHEN LATHAM: So moved.

5 DR. FISHBONE: Seconded.

6 CHAIRMAN GALVIN: Okay. Any discussion on
7 this? If not, all in favor indicate by saying aye?

8 ALL VOICES: Aye.

9 CHAIRMAN GALVIN: The motion is carried.

10 Thank you.

11 MS. HORN: Okay. Then I guess we're moving
12 to Item 6, the ethics and law subcommittee update. And
13 which I thought Julius was going to be here to provide
14 this, but is not. So the issue on the table is that we --
15 CI has received some information on the Evergen escrow and
16 that approval of that is before the Committee. The ethics
17 and law subcommittee had a meeting a couple of weeks ago
18 where the issue first was raised following a question
19 about whether Evergen had received escrow approval. And
20 we determined that they had just indeed submitted that the
21 day before.

22 So the ethics and law subcommittee has
23 reviewed the materials, has made some comments that were
24 in your packets. I believe at least one member is on the

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1 phone. And so the -- that is the item up for discussion
2 today about whether -- what are the problems with the
3 escrow approval.

4 MS. NEWTON: Are we being asked? I
5 hesitate to be so ignorant about the whole thing. The --
6 are we being asked to decide whether or not we should
7 accept this particular escrow as to say it's in our
8 jurisdiction? Or -- the answer to that would seem to be
9 clearly not. Or is the question should we form our own or
10 is the question should we develop criteria for any escrow
11 other than the university escrow?

12 MS. HORN: It's really a very narrow issue
13 that we're looking at today for this subcommittee in which
14 the subcommittee would like your input on whether the
15 materials that were submitted by Evergen on the escrow,
16 the policies and procedures and its approval are
17 acceptable.

18 MS. NEWTON: Then Evergen is -- they say
19 they're looking at biomed escrow?

20 MS. HORN: And this is Lisa Newton
21 speaking.

22 MS. NEWTON: Yes, this is Lisa Newton. And
23 we're taking a look at the acceptability of Biomedical
24 Research Institute of America, Embryonic Stem Cell

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1 Research, is that what we're doing?

2 MS. HORN: Yes.

3 MS. NEWTON: Okay.

4 CHAIRMAN GALVIN: But there is a comment
5 that the Committee would like to disapprove this escrow
6 and stating that the escrow membership does not meet NAS,
7 which I -- the National Academy of Science, I presume,
8 does not meet NAS guidelines regarding the expertise. So I
9 think that, Lisa, this one comes down to a question of a
10 subcommittee has met and doesn't feel that this particular
11 escrow membership -- it doesn't meet appropriate
12 guidelines so they're basically disqualifying the escrow
13 for this particular -- that met on this particular grant.
14 And I think that this is at the point we wanted to have
15 some discussion about where that's -- where do we do.
16 Since the Committee has disapproved them what do we have
17 to say as a group about -- the subcommittee has
18 disapproved them.

19 MS. NEWTON: Okay. So the subcommittee --
20 the subcommittee that I'm on?

21 MS. HORN: Yes.

22 DR. WALLACK: Lisa, if you can --

23 MS. NEWTON: -- we have already disapproved
24 this?

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1 MS. HORN: No, no. There has not been
2 another meeting. The subcommittee had some discussion that
3 was not official discussion, but indicating that there
4 were some issues with the escrow and were invited to this
5 meeting to share those concerns with the Committee and
6 then this Committee will make a decision about whether the
7 escrow, the materials are deficient in some way and
8 perhaps provide some feedback to --

9 MS. NEWTON: -- the committee that I am on
10 is to -- or has been charged with looking over this
11 material and making a recommendation to you, but you are
12 the ones that are going to make the decision.

13 MS. HORN: That's correct.

14 CHAIRMAN GALVIN: That's correct.

15 MS. NEWTON: Okay. Am I the only one that's
16 here?

17 MS. HORN: Ann Hiskes is apparently is on
18 her way. She is the escrow chair for UCONN.

19 MS. NEWTON: Yes, I know.

20 MS. HORN: And I'm telling the Committee
21 and, Lisa, you are a bioethics are Fairfield University,
22 is that correct?

23 MS. NEWTON: Yes, I am.

24 MS. HORN: Okay.

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1 DR. LATHAM: And I'm also, Steve Latham,
2 I'm also a member of that subcommittee. I did not attend
3 the last meeting, but I have been reading the materials as
4 we've been sending them back and forth by e-mail.

5 DR. KIESSLING: And this is Ann Kiessling.
6 I'm in the same situation as Steve. I'm a member of that
7 subcommittee, but I missed the last meeting.

8 MS. NEWTON: Okay.

9 DR. PESCATELLO: Can I ask you a question?
10 What's the procedure though? So on the approving of
11 escrow arrangements so are they approved as part of the
12 application process? I mean so how did this come to this
13 subcommittee? Does the subcommittee review all escrow
14 arrangements or did something happen that -- just
15 procedurally how did this -- why are we in this position?

16 MS. NEWTON: My understanding of it and I
17 did not have a -- I haven't really had a chance to comment
18 on this before today, but my understanding from the last
19 meeting was there are for profit escrows out there,
20 commercial escrows.

21 DR. PESCATELLO: Correct.

22 CHAIRMAN GALVIN: Yes.

23 MS. NEWTON: We wonder what kind of a job
24 they are doing. I think this is a matter of some concern.

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1 So let's take a look at what's going on. So this, I
2 gather, is the only one that's come in and it's kind of a
3 joke.

4 MS. HORN: Well, Lisa, before we get to
5 that, I think that just the procedural question that Paul
6 is asking. So the ethics and --

7 MS. NEWTON: -- why am I on this phone?
8 What I am asked to be -- to talk about?

9 MS. HORN: What we're interested in is your
10 opinion as a bioethics about the sufficiency of the
11 materials that were submitted by Evergen. But there was a
12 procedural question that one of the members of the
13 Committee had asked about this process, why is this
14 particular issue coming to this Committee through the
15 ethics and law subcommittee, which is not how the escrow
16 approvals have typically happened. Most of the escrow
17 approvals take place in an institution with an
18 institutional escrow. This is the first time we have
19 looked at a commercial entity putting together an escrow
20 and the ethics committee, subcommittee took it on to look
21 at whether they could provide this Committee, the
22 subcommittee -- or the Advisory Committee with their
23 expertise on this particular issue.

24 CHAIRMAN GALVIN: Okay, let me just see if

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1 I can -- if I can understand it. This is -- this
2 particular escrow group has fallen under surveillance
3 because it's not part of a usual university setup and
4 since we're in a small state we know all the universities,
5 all three of them involved. So because it's different it
6 has fallen into -- because it was different it got
7 scrutinized and apparently that scrutiny took place by the
8 law and the ethics committee.

9 MS. NEWTON: Right.

10 DR. PESCATELLO: So normally --

11 DR. LATHAM: -- Steve Latham on the phone,
12 I'm afraid I have to bow out of the call now. I wanted to
13 say one thing, well maybe two quick things before I have
14 to leave. One is that I agree with the recommendation
15 that this escrow's approval not count for reasons that I'm
16 sure that Lisa could tell you and that are memorialized in
17 the mail from Audrey that you have in evidence there.

18 But in addition to that I've looked at the
19 Chair of the escrow committee is a fellow called Fred Fox,
20 JD, and in the records of the California Bar Association
21 Fred Fox, JD is not likened to practice law because he
22 stopped keeping up with his continuing professional
23 educating requirements and did not pay his bar dues as of
24 2007.

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1 CHAIRMAN GALVIN: Is that bad?

2 DR. LATHAM: So although he is a JD, he is
3 not currently licensed. I'd just add that to the mix of
4 the bizarre features of this escrow that's been approved.

5 DR. PESCATELLO: Steve, if you can just
6 stay on for a second. I just have a question. So the -- so
7 that normally when one applies for a grant from, under the
8 stem cell research program in Connecticut you identify the
9 type of escrow you will be using in that application
10 process? And so as part of --

11 DR. LATHAM: -- I'm told that any escrow
12 that wasn't either the UCONN or the Yale escrow has been
13 used.

14 DR. PESCATELLO: Right.

15 DR. LATHAM: And so this is the first time
16 we've ever had to think about criteria and check and see
17 whether there was escrow criteria or beyond NAS
18 guidelines. It's odd because we had no question about the
19 Yale and the UCONN escrow.

20 DR. PESCATELLO: This is an approved
21 proposal -- this is -- this is something that's already
22 been approved.

23 DR. LATHAM: Approval of it is contingent
24 upon --

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1 CHAIRMAN GALVIN: -- contingent.

2 DR. LATHAM: On getting escrow approval.

3 DR. PESCATELLO: Right.

4 CHAIRMAN GALVIN: They're all contingent on
5 escrow approval. Thanks Steve.

6 MS. HORN: And, generally, that falls under
7 -- you're right, the escrow approval and review of
8 policies and procedures takes place at an administrative
9 level and we -- because it's at the institutional escrows
10 that we're dealing with. But this was a different
11 category.

12 CHAIRMAN GALVIN: Now, can we limit our
13 discussion to listening to Lisa and the others tell us why
14 they don't want to approve this escrow committee and then
15 what -- if we accept that then move on to the next step
16 rather than discussing escrow and this guy who maybe for a
17 valid reason doesn't keep his license up, etcetera.

18 DR. PESCATELLO: I'm just trying to understand
19 why wasn't this done at the application process?

20 CHAIRMAN GALVIN: It never is.

21 DR. PESCATELLO: It never is. I mean so
22 people said they were going to use --

23 CHAIRMAN GALVIN: -- no, they don't do it
24 until they get the grant.

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1 DR. PESCATELLO: And they don't --

2 CHAIRMAN GALVIN: -- yes, they do the
3 grant. So if you and I came up with a grant and figured
4 out, the hell with it, we'll get the escrow after -- if we
5 get the grant we'll get the escrow, if not why bother.

6 DR. PESCATELLO: Okay.

7 MS. NEWTON: That makes sense.

8 CHAIRMAN GALVIN: Okay. Yes, Bob.

9 MR. MANDELKERN: Dr. Galvin, I'm just
10 puzzled about one thing, in the minutes that we approved
11 just before the meeting, the minutes of the July 23
12 Advisory Committee meeting on page five discussions ensued
13 on the Evergen project. Ms. Wagner stated that escrow
14 approval is still pending and the PI has contacted UCONN
15 and a commercial entity with respect to escrow review of
16 the project.

17 CHAIRMAN GALVIN: Okay.

18 MR. MANDELKERN: I am wondering -- I
19 understand -- I've seen all the material and I read it
20 carefully about the commercial entity with respect to
21 escrow. Has there been --

22 MS. NEWTON: -- I'm sorry.

23 CHAIRMAN GALVIN: Commercial entity with
24 respect to escrow.

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1 MR. MANDELKERN: Has there been any report
2 about Evergen's attempt to contact UCONN for escrow?

3 CHAIRMAN GALVIN: Okay, Bob, that's --
4 you're getting a little too far field. We're talking about
5 this one escrow entity and whether or not it's an
6 acceptable entity or not. If it is that's one thing, if
7 it isn't then we go on to other some alternative. Yes,
8 Milt.

9 DR. WALLACK: Bob, would it put a context
10 to the conversation if -- would it put a context to the
11 conversation if a motion were to be made that could then
12 be discussed about all this because that was the case I
13 would make such a motion to reject the escrow group as
14 part of this application.

15 CHAIRMAN GALVIN: All right. I think
16 that's -- I'll second that motion.

17 DR. WALLACK: Okay.

18 CHAIRMAN GALVIN: And they're all in favor,
19 all in favor of -- we need a discussion, I'm sorry, excuse
20 me. Now, we're going to discuss the motion on the floor is
21 to reject the escrow. What's the name of the company? Do
22 we have a name?

23 DR. WALLACK: Yes, we do. It's biomed.

24 CHAIRMAN GALVIN: The biomed escrow. Okay.

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1 And then we're going to vote yes or no. We're either going
2 to accept it or reject it. So now we're open for
3 discussion. I usually like to make the vote and then
4 discuss it afterwards.

5 DR. PESCATELLO: The subcommittee is
6 recommending, right?

7 CHAIRMAN GALVIN: The subcommittee is
8 recommending rejection.

9 DR. PESCATELLO: Rejection.

10 MS. NEWTON: Yes. I join in the
11 committee's recommendations for exactly the same reasons
12 that have already been given. The people seem to be
13 totally unqualified, at least -- I haven't seen a vitae of
14 course, but they just don't seem to be the right kinds of
15 people for this sort of committee. Most of the committee
16 membership that requires expertise is vacant. It's headed
17 up by a person with dubious credentials in several
18 respects. And I see no reason to delay over saying,
19 whatever we meant this isn't it.

20 CHAIRMAN GALVIN: That's a good comment.

21 DR. ERNIE CANALIS: Commissioner, this is
22 Ernie.

23 CHAIRMAN GALVIN: Ernie, Ernie, you can't
24 talk about this one.

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1 DR. CANALIS: Why?

2 MS. HORN: This is part of the review of
3 this grant that you did not vote on. You recused yourself
4 from the Evergen vote, I believe.

5 DR. CANALIS: Why?

6 MS. HORN: And this is a part of the
7 continuing -- why did you rescue yourself or why -- why
8 now?

9 DR. CANALIS: Why did I rescue myself?
10 This is part of the University of Connecticut?

11 MS. HORN: No.

12 DR. WALLACK: Ernie, this is Milt speaking.
13 If there is a problem of -- Bob, would it be appropriate
14 for one of the people at the table to read Dr. Canalis'
15 remarks into the record because there was an e-mail
16 transmission that Dr. Canalis was part of it. So if he
17 can't comment can one of us comment and quote him?

18 CHAIRMAN GALVIN: No. You can't do that.

19 DR. CANALIS: If I rescued, I rescued. I
20 did not remember, I'm sorry. That is fine, not a problem.

21

22 CHAIRMAN GALVIN: Okay.

23 MS. HORN: Thank you.

24 CHAIRMAN GALVIN: All right, let's move on.

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1 I think Lisa has stated this very succulently, but Paul.

2 DR. PESCATELLO: So has Evergen been
3 informed of this conclusion or this recommendation and
4 given a chance --

5 CHAIRMAN GALVIN: -- we haven't done it.

6 DR. PESCATELLO: But of the committee -- I
7 mean so we're --

8 CHAIRMAN GALVIN: -- this is it. They'll be
9 informed after we -- if they need to be informed they can
10 be --

11 DR. PESCATELLO: - when they were analyzing
12 whether this escrow was valid or not they talked to
13 Evergen and --

14 MS. HORN: -- no, the way this took place,
15 just so that we're all clear, there was an ethics and law
16 subcommittee meeting and at the end of the meeting there
17 was a question asked about whether Evergen had submitted
18 their escrow materials. And the answer to that was, yes,
19 yesterday. So the materials were sent out to the
20 subcommittee and the subcommittee has not subsequently
21 met. So although they have sent one another some
22 information there has been no discussion about that. The
23 discussion is occurring here today. So while the -- they
24 will share with you the tone of their -- of their e-mail,

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1 that needs to take place on the record. And so they have
2 not made an official decision at the subcommittee level,
3 but they're sharing their expertise with us here today.

4 MS. NEWTON: Once again, what would it take
5 to get a -- an official decision at the subcommittee level
6 given that we don't seem to be around the same table?

7 MS. HORN: We'd have to have another
8 meeting, Lisa, and have that. And in the interest of time
9 the --

10 MS. NEWTON: -- I don't think we need
11 another meeting, not for this.

12 MS. HORN: Correct. And you're here to give
13 us your thoughts, which you've done.

14 MS. NEWTON: Which I've done.

15 MS. HORN: Great.

16 CHAIRMAN GALVIN: Okay. Any further
17 discussion?

18 MS. AUDREY CHAPMAN: This is Audrey
19 Chapman. I just joined the conversation and I am one of
20 the several people who raised questions about the Evergen
21 escrow.

22 MS. HORN: And, Audrey, can you just tell
23 us your background for the group?

24 MS. CHAPMAN: I hold a Healy Chair in

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1 medical humanities and ethics at UCONN in the Department
2 of Community Medicine.

3 MS. HORN: Okay.

4 MS. CHAPMAN: And I've been on the UCONN
5 escrow from the very beginning and I do research and
6 writing on the ethics of stem cell issues.

7 CHAIRMAN GALVIN: Okay. I think we've
8 heard good and valid testimony that this simply doesn't
9 meet our needs. I don't know what else you might want to
10 do. And --

11 DR. PESCATELLO: -- so the subcommittee has
12 issued a report, they've put something in writing?

13 CHAIRMAN GALVIN: Well, no, no. The
14 subcommittee needed to meet subsequently if they were
15 going to put something in writing. But we're hearing from
16 members of the subcommittee who are bona fide bio
17 ethicists that it simply doesn't meet. I mean either --

18 MS. NEWTON: -- it doesn't do it.

19 CHAIRMAN GALVIN: It doesn't do it, that's
20 all.

21 DR. WALLACK: Bob, to facilitate this can
22 we call the question because we have a motion on the
23 floor?

24 CHAIRMAN GALVIN: Yes, I think --

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1 DR. WALLACK: -- can I call the question
2 then?

3 CHAIRMAN GALVIN: Do you have a comment?

4 MR. MANDELKERN: Can I ask a question of
5 Ms. Chapman?

6 DR. PESCATELLO: Procedurally that -- I
7 mean I fully would endorse what I understand from the
8 reputations around the subcommittee that it sounds like a
9 very inadequate escrow. But I just wondered two things,
10 first I wondered about Evergen itself getting notice and
11 having a chance to explain itself. It doesn't sound like
12 it would be able to, but I don't think -- if given a
13 chance. And we're acting on people over the telephone. I
14 don't have anything in writing other than people saying
15 it's a terrible escrow.

16 DR. WALLACK: Well, some of us have read
17 these.

18 CHAIRMAN GALVIN: Watch would turn this
19 into an acceptable escrow? How could it --

20 MS. NEWTON: -- well, -- (inaudible) -- and
21 if Evergen would like to -- if there is any reason for
22 Evergen to want to get in our good graces and it wishes to
23 answer the complaints in the e-mails, and I have no new
24 ones, I don't see why on earth they shouldn't be able to.

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1 CHAIRMAN GALVIN: Well, if the -- if this
2 escrow is considered inappropriate then Evergen can do
3 whatever they think you know, whatever they think is
4 reasonable and proper, but we'd have to set a timeframe. I
5 mean we can't give them another year to decide how they're
6 going to get this thing looked at.

7 MS. NEWTON: Are we ever using this escrow?

8
9 CHAIRMAN GALVIN: No, we've never used it
10 before. Everything else has been either a UCONN or a Yale
11 subset. And so they've used their own internal escrows.
12 This is the first time we've had somebody who didn't
13 belong to one of the other of the institutions or wasn't
14 commingled with a Wesleyan, with a Wesleyan effort. So
15 they'd gone and found one and what -- I think what we're
16 talking about is saying that we don't think it's
17 acceptable, so you'll have to do something else.

18 MS. NEWTON: Right, okay. Is there -- I'm
19 looking is there a proposal out there that's hanging out
20 to dry thinking that it's got an escrow and it doesn't?

21 CHAIRMAN GALVIN: They know they don't have
22 an escrow. And if they don't want it to not only hang out
23 to dry, but to dry they'll get themselves, you know, an
24 acceptable escrow. And, you know, we're talking as I

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1 always -- you haven't heard me say this before, everybody
2 else has, they'll all groan, but this is taxpayer's money
3 and, you know, I'm not here to fool around with it. They
4 either meet it or they don't meet it. If they don't meet
5 it they'll have to find another alternative. And if we're
6 going to have experts on our panel and they tell us it
7 doesn't meet it, then I'm not going to say, well, you
8 know, perhaps maybe, if and --

9 MS. NEWTON: -- I like that idea.

10 CHAIRMAN GALVIN: Okay. We don't have the
11 responsibility for the escrow. Mr. Mandelkern, did you
12 have a remark?

13 MR. MANDELKERN: Yes, Dr. Galvin. Can I
14 address a question to Professor Chapman from UCONN?

15 CHAIRMAN GALVIN: Are you still there
16 Professor Chapman?

17 MS. CHAPMAN: Yes, I am.

18 CHAIRMAN GALVIN: Yes.

19 MR. MANDELKERN: May I?

20 CHAIRMAN GALVIN: Certainly.

21 MR. MANDELKERN: Professor, according to
22 our minutes Evergen, which is the first commercial entity
23 we've ever funded or granted an award -- awarded a grant,
24 excuse me, was supposed to have contacted UCONN about

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1 escrow. To your knowledge, did Evergen ever contact UCONN
2 about escrow?

3 MS. CHAPMAN: I think that the person who
4 is the Chair of the proposed escrow did call Professor
5 Hiskes, who is the Chair of our escrow and at some point
6 this summer when she was on vacation and spoke to her
7 then. I know that at one point Evergen was hoping that
8 the UCONN escrow could have oversight, but in Professor
9 Hiskes' doing some consultation at the highest levels that
10 is not feasible because No. 1, it -- Evergen is not the
11 UCONN campus, does not involve University of Connecticut
12 faculty. And the President of UCONN said that it would No.
13 1, be unacceptable in terms of the liability issues. And
14 secondly that UCONN would not the means to do follow up
15 monitoring.

16 CHAIRMAN GALVIN: Lisa, I'm getting a lot
17 of feedback from your phone. Maybe --

18 MS. NEWTON: -- I'm sorry.

19 CHAIRMAN GALVIN: Yes.

20 MS. NEWTON: I'm just wondering if the
21 Evergen would have had to find itself an escrow this -
22 found this escrow, this escrow was not acceptable, now it
23 has to find another escrow. The University escrows aren't
24 going to go near Evergen because of liability and

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1 monitoring problems. Should we be thinking about putting
2 ourselves together an escrow for the state?

3 CHAIRMAN GALVIN: No.

4 MS. NEWTON: No.

5 DR. WALLACK: I think, frankly, this is
6 somewhat extraneous -- this is somewhat extraneous to the
7 conversation, to the vote that's in front of us. However -
8 -

9 MS. NEWTON: -- yes.

10 DR. WALLACK: -- however, for the record,
11 we just had an interstate alliance meeting in Baltimore
12 and this -- of those states that are involved with stem
13 cell research. And what was put on the table was this
14 same exact discussion. And we -- the discussion ended on
15 the basis of we can't go forward with the universities
16 being expected to do this because of the liability, and
17 also of the monitoring. And also the third part of it is,
18 which is an extension of the monitoring, what control do
19 they have? They have none on a commercial undertaking as
20 opposed to what they have at the university where they can
21 close down the project.

22 MS. NEWTON: Right.

23 DR. WALLACK: So when Commissioner Galvin
24 says no, I totally agree and this is an amplification of

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1 why I totally agree. Having said all of that, the IASCR,
2 this interstate alliance, supposedly might be looking into
3 ways of having, in the future, further consideration on
4 the basis of the universities doing something about a more
5 extended escrow consideration that's not in existence
6 right now, however.

7 MS. NEWTON: Okay. So we don't -- if a
8 company says, well, you know, that wasn't a good, what do
9 we do, where do we go for escrow approval, we have nothing
10 to say to them, do we?

11 CHAIRMAN GALVIN: Okay. Hang on.

12 MS. HORN: What I'd like to do now
13 procedurally, just to make the record more clear in terms
14 of what has been offered from the subcommittee members who
15 we may not have heard from --

16 CHAIRMAN GALVIN: -- incidentally Ann
17 Hiskes has just joined us for those of you who can't see
18 through the telephone.

19 MS. NEWTON: Okay.

20 MS. HORN: This is material that was
21 distributed to the Committee as part of their packets and
22 is a letter from Ann Hiskes to CI, and a couple of e-mails
23 back and forth from Audrey Chapman, Ann Hiskes, and -- we
24 will enter those documents into the record, so to speak,

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1 and have them available as the basis for the
2 subcommittee's comments. They're just fleshed out a little
3 bit more from the discussion we've had here today.

4 CHAIRMAN GALVIN: Yes. I think it's obvious
5 that this is a matter that needs more elucidation and
6 discussion not only in the content of escrows that may
7 have to make judgments and comments about commercial
8 ventures, but also in liability protection or liability
9 acknowledgement and the ability to follow through. And so
10 it looks to me like it's a very difficult and multi
11 faceted question which will need some time, probably, from
12 the interstate committee and others to describe some ways
13 to do this so we don't squeeze people off simply because
14 they can't, they can't piggyback on a university and they
15 can't figure a way to get their own appropriate one.

16 Many times in situations like this rump
17 organizations arise just to do it and to put the stamp on
18 it, which may or may not be effective or meet or needs.
19 My needs are -- is that it's an Evergen problem. It isn't
20 our problem. I'm trying to dispense -- I'm trying to
21 dispense money. I can't have money sitting around
22 particularly in these very tough economic times and so we
23 have to let them know what our decision is. If it is a
24 negative decision then we have to give them, I would

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1 think, 60 days or so to try to solve it on their own. If
2 they don't, we might have to go to the next eligible
3 grant. This is business.

4 DR. WALLACK: Can I call the question on
5 the motion to reject?

6 CHAIRMAN GALVIN: Yes.

7 MR. MANDELKERN: Reject this particular
8 escrow.

9 CHAIRMAN GALVIN: The escrow.

10 MR. MANDELKERN: This particular one.

11 CHAIRMAN GALVIN: This particular escrow of
12 the Evergen grant not to say that at some time in the
13 future should they find an appropriate one that we would
14 not reconsider with -- and I think we would next have to
15 have a vote of a how long will they get to try to fix one.

16 I can't hold the money forever for them. So the motion
17 on the floor is -- as to whether or not we're going to
18 accept this escrow or reject this escrow. So a yes vote
19 means, yes, we're rejecting this -- a positive vote. And
20 aye indicates we're rejecting this escrow. Has everybody
21 got that?

22 MR. WOLLSCHLAGER: Maybe just one point of
23 clarification or question really.

24 CHAIRMAN GALVIN: Yes.

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1 MR. WOLLSCHLAGER: We're not -- we're
2 rejecting this escrow for this applicant.

3 CHAIRMAN GALVIN: Yes.

4 MR. WOLLSCHLAGER: We're not making this
5 escrow company downstream may very well be --

6 CHAIRMAN GALVIN: -- may change.

7 MR. WOLLSCHLAGER: A good escrow.

8 CHAIRMAN GALVIN: Yes.

9 MR. WOLLSCHLAGER: So it's just for this.

10 DR. WALLACK: Specially this.

11 CHAIRMAN GALVIN: Okay. Now, I'm going to
12 call all in favor, all in favor means that if you are in
13 favor of rejecting this particular escrow for this
14 particular firm at this particular time, please, indicate
15 by saying aye.

16 ALL VOICES: Aye.

17 CHAIRMAN GALVIN: Okay. Any opposed? The
18 motion is carried. The escrow is rejected for Evergen. Do
19 we want to give them a time to find an alternate?

20 DR. WALLACK: I would give them no more
21 than 30 days. This -- we originally put the application --
22 -- made the award in April. We've had discussions in June
23 and July. As I recall we've had -- we had a number of
24 other applications for funds that were very, very close.

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1 CHAIRMAN GALVIN: Yes.

2 DR. WALLACK: That we needed to reject. The
3 year is going by.

4 CHAIRMAN GALVIN: Would you give them 45?

5 DR. WALLACK: Frankly I would -- if -- in
6 all honesty, in all honesty I would give them -- I would
7 give them 25 only -- only because I would like to then, if
8 I gave them 25 --

9 CHAIRMAN GALVIN: -- 45.

10 DR. WALLACK: I understand. I understand.

11 CHAIRMAN GALVIN: All right. I just wanted
12 to let them not to be able to argue that we didn't give
13 them enough time.

14 DR. WALLACK: Okay, okay. I understand.

15 CHAIRMAN GALVIN: They need to be noticed
16 immediately, but --

17 DR. WALLACK: -- so I would move that we
18 give them 45 days to come back with clarification. And
19 that would enable us, Bob, to at least act on this no
20 later than the November meeting.

21 CHAIRMAN GALVIN: Do we need to vote on
22 that?

23 MR. MANDELKERN: No. I would like to speak
24 on it, if I may.

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1 CHAIRMAN GALVIN: Okay. Do we need a vote
2 on it?

3 MR. MANDELKERN: Yes, I think we do.

4 CHAIRMAN GALVIN: Okay, yes.

5 MR. MANDELKERN: I would argue to give this
6 grant, which we awarded and have not funded because of the
7 lack of escrow, a little more time than 45 days. It is a
8 ground breaking grant if they can find proper escrow. If
9 they can't, they do not get dollars.

10 CHAIRMAN GALVIN: Tell them to hurry up. 45
11 days --

12 MR. MANDELKERN: -- can I finish my
13 statement, please?

14 CHAIRMAN GALVIN: Yes.

15 MS. NEWTON: Commissioner?

16 CHAIRMAN GALVIN: Yes.

17 MR. MANDELKERN: Can I finish my statement,
18 please?

19 CHAIRMAN GALVIN: Yes. Go ahead.

20 MR. MANDELKERN: May I?

21 CHAIRMAN GALVIN: Go ahead.

22 MR. MANDELKERN: This Company is struggling
23 under an unusual burden. One of its founders and guiding
24 lights, Jerry Yang, is dying of cancer as we sit. So

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1 they've lost their leading guide and mentor. I say give
2 them 90 days. If they don't come in, obviously, they have
3 to go find an institutional commercial escrow. The
4 universities will not do it. That is clear. I don't think
5 we have to discuss that. I would give them 90 days to find
6 a suitable escrow commercially or the grant is rescinded.

7

8 CHAIRMAN GALVIN: Okay. Let me comment.
9 Let me comment on that remark. I wouldn't give them any
10 more than 45 days. I think 45 days is a gift. I'm sorry
11 that they have problems. As they used to say during the
12 Great Depression, things are tough all over. And bad
13 things happen to people. Keep -- principal players are
14 lost. This is business and this money is sitting there
15 while other people can't do the research.

16 DR. WALLACK: I'll move 45 days on the
17 floor as a motion.

18 CHAIRMAN GALVIN: Okay, I'll second that.
19 Any further discussion?

20 DR. TREENA ARINZEH: This is Treena
21 Arinzeh. Can we make a recommendation for an escrow? You
22 know in the letter that we send like here are some -- a
23 list of possibilities. Maybe they just don't know
24 qualified escrows.

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1 MS. HORN: I think we try a little bit of a
2 fine line there in terms of it coming across as an
3 endorsement. I think that there is a way of indicating
4 that there are efforts out there that we're aware of, of
5 escrows that are attempting to be formed and make them
6 aware of some of that information that they can pursue on
7 their own.

8 MR. WOLLSCHLAGER: We could also give them
9 the names of other states that have funded private
10 applicants. And some have -- some have figured out how to
11 solve this problem. We haven't yet, but some other states
12 have.

13 MS. HORN: Yes, no, that's a good point.

14 MR. WOLLSCHLAGER: And just a clarification
15 if I may then.

16 CHAIRMAN GALVIN: Sure.

17 MR. WOLLSCHLAGER: Well, not even a
18 clarification, a question, we're not saying that Evergen
19 could not reapply next year.

20 CHAIRMAN GALVIN: We're not saying
21 anything. We're just saying, you didn't get the proper
22 escrow and you've got 45 days to get it. If you don't your
23 grant goes away.

24 MR. WOLLSCHLAGER: Okay.

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1 CHAIRMAN GALVIN: I mean this is business.
2 We've got to get some business done and we've got to get
3 the money out to people. I can't keep waiting around the
4 better part of a year while somebody gets themselves on
5 track for whatever reason. I'm sorry they've had problems.
6 I'm sorry Jerry is ill, but etcetera.

7 DR. PESCATELLO: What is a reasonable time
8 for somebody to find a replacement escrow?

9 CHAIRMAN GALVIN: How much money is this?
10 900,000 dollars, let me tell you, if it was me I'd be
11 working 24 hours a day, seven days a week. I'd make very
12 sure I had an escrow in about 30 days, the end of the
13 week, you've got it.

14 MR. MANDELKERN: Have we heard from Dr.
15 Hiskes?

16 DR. ANNE HISKES: Two points, one is -- I
17 have two points. I'm -- I don't know if there are any
18 commercial escrows. I don't know if they have a solution
19 other than forming their own in some way and I'm not sure
20 how that would -- how that would work, who they would get.

21
22 California law, as I'm told by colleagues
23 in California, does not permit the payment of escrow
24 members and that's why the commercial IRB's in California

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1 have not formed escrows. And I think this just going to
2 be a problem.

3 My second point is that this grant was
4 awarded April 1st, I believe. I was told like April 5, by
5 somebody, oh, they're going to approach UCONN for
6 approval. They're going to approach UCONN for approval. So
7 I'm sitting there waiting. May passes, June passes. I'm
8 now on my vacation in July. It's July 9. I get a call
9 from somebody associated with the company. So we talk
10 briefly. This is not a good sign.

11 CHAIRMAN GALVIN: Yes, for 9/10ths of a
12 million dollars one would be a little bit more --

13 DR. HISKES: -- so I'm just I think 45 days
14 is a gift.

15 CHAIRMAN GALVIN: A gift. Okay. All in
16 favor -- now there is a motion on the floor to give them -
17 - to give Evergen 45 days to find an acceptable escrow.
18 Warren is going to provide them with the names of states
19 who apparently have solved this, but I think that's all
20 right, but we're going to give them 45 days at which time
21 the grant will be reallocated. Everybody understand that?
22 All in favor indicate by saying aye.

23 ALL VOICES: Aye.

24 CHAIRMAN GALVIN: Opposed?

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1 MR. MANDELKERN: Opposed.

2 CHAIRMAN GALVIN: Okay. One negative vote,
3 the motion is carried.

4 DR. KIESSLING: Commissioner?

5 MR. MANDELKERN: Yes, Ma'am.

6 DR. KIESSLING: This is Ann Kiessling. I
7 want to follow up a lintel bit and I'm glad that Anne
8 Hiskes is in the room there.

9 CHAIRMAN GALVIN: So am I.

10 DR. KIESSLING: The reason that the UCONN
11 escrow cannot consider grants from private entities, it's
12 a liability issue.

13 DR. HISKES: I spent most of yesterday
14 trying to get input from the President's office and the
15 Vice President's office. And they're just a national --
16 first of all a national policy among IRB's that you can't
17 take on the responsibility of oversight for research that
18 you can't control, that you can't monitor, that you have
19 no leverage in. Let's say that someone is not compliant
20 you can speak with the people. You can say if you don't
21 become compliant we can cut off your funds. We can lock
22 your lab, whatever.

23 And it doesn't matter if say if the
24 university were given indemnity, but if it's known to be

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1 the escrow of record and, you know, something unsavory
2 happens the reputation of the university is besmirched.
3 And so the -- my institution is very adamant that this is
4 -- has been their policy all along. Their IRB's don't
5 oversee work done off campus by people who are not their
6 employees. If it's off campus and they're employees at
7 least you have a lever you can use and you make sure that
8 there is some on site monitoring or reporting.

9 DR. KIESSLING: So this is exactly the
10 problem that nobody wanted to happen when escrow
11 committees were proposed. That nobody wanted them to be
12 elevated to the level of responsibility that IRB's have.
13 And IRB's, of course, have the level of responsibility of
14 the safety of the same subject. That's not even in the
15 purview of an escrow committee or what's hoped for. But
16 if that's your institution's position I mean, you know, we
17 could certainly argue that with them because I think it's
18 going to take all small entities in Connecticut at a huge
19 disadvantage.

20 DR. HISKES: The escrows are agents of the
21 universities as they are --

22 CHAIRMAN GALVIN: -- yes, well, the new
23 university structure and the current provost you would
24 have no chance. I mean you have a better chance of

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1 observing the sirens of Titan and space then you would
2 have of getting the provost to -- he wouldn't even
3 consider that unless I've totally misread him.

4 DR. KIESSLING: But in this particular case
5 this little entity was, in fact, under the umbrella of the
6 University of Connecticut for a while, correct, this
7 little company?

8 DR. HISKES: That was in the incubator
9 state.

10 DR. KIESSLING: So this little company I
11 think the mistake they made was to leave the university
12 system.

13 CHAIRMAN GALVIN: I think that was an
14 informed decision. And I'm sure that they, in the process
15 of making that decision, being established researchers
16 they knew that they were going to incur some risks and
17 this is one of the risks that they have incurred. Prior
18 to their leaving the structure of the university has
19 changed so that the provost is now the person who oversees
20 all research from medieval art history to stem cell. And
21 the provost is a very pleasant gentleman, but he makes --
22 he's very exacting and you have no difficulty in
23 understanding where he is on these matters. I know he
24 would never -- unless I've totally misread him that he

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1 would never consider anything like this that would put the
2 university at risk in any form.

3 So somehow - and if there are monies like
4 9/10ths of a million dollars, or a million dollars, or a
5 quarter of a million dollars that are potentially
6 available you can believe the commercial entities will
7 find a way to solve the problem.

8 DR. KIESSLING: Well, I think this is a
9 small non-profit now.

10 CHAIRMAN GALVIN: I think pardon?

11 DR. KIESSLING: I think that this little
12 company is now a non-profit, isn't that correct?

13 MR. MANDELKERN: Yes.

14 CHAIRMAN GALVIN: It doesn't make any
15 difference I don't think for escrow, does it? No.

16 DR. KIESSLING: That clarifies that.

17 Thanks, Anne.

18 DR. HISKES: Sure.

19 CHAIRMAN GALVIN: Okay. Any further
20 comment? I think we have one or two other agenda items.

21 MS. NEWTON: Can I hang up now?

22 CHAIRMAN GALVIN: Thank you very much,
23 Lisa.

24 MS. NEWTON: Okay.

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1 MS. CHAPMAN: This is Audrey, I'm also
2 hanging up.

3 CHAIRMAN GALVIN: Thank you very much for
4 your contribution.

5 DR. PESCATELLO: Could we briefly go over
6 the goings on of the strategic planning committee. We met
7 in the summer on July 11th and on September -- just
8 recently on September 8th. I should just start off by
9 saying as we talked about the sort of long term issues of
10 the Connecticut Stem Cell initiative we did focus a little
11 bit on some shorter term problems and sort of the most
12 pressing in a sense are the vacancies on this very
13 Committee of things not sometimes -- meetings not being
14 able to be held because of some vacancies. And I know that
15 the administration of DPH is working on that and getting
16 word out to the appointing authorities, but there are
17 outstanding appointments that have to be made.

18 We've also spent a fair amount of time
19 talking about the administrative costs of the stem cell
20 program in Connecticut through DPH, CI. We've looked --
21 Warren Wollschlager has given us some very good data on
22 what's going on in other states in terms of percentage of
23 dollars of the overall awards that are spent on
24 administration. And it's something in the order of 3 to 5

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1 percent seems like the norm, which is a very small amount
2 when you consider the amount that other universities take
3 for administrative expenses for the grants. And we will be
4 crafting a formal recommendation on that -- on those
5 administrative costs.

6 We also spent some time talking about the
7 peer review process and specifiably the compensation issue
8 for the peer reviewers that we're going to, at some point
9 it's going to be very hard to get peer reviewers without
10 being able to compensate their expenses. And, again,
11 Warren Wollschlager has provided some of the data on that
12 and I think there is a proposal out there right now to, in
13 fact, have compensation.

14 MR. WOLLSCHLAGER: Yes, I'm not sure if you
15 were here. No, you weren't here when the Commissioner made
16 his remarks that we actually got the sign off from --

17 DR. PESCATELLO: -- oh, good.

18 MR. WOLLSCHLAGER: From administrative
19 services to enter into PSA's with the reviewers, not for a
20 lot, for an amount ranging from 100 to 400 per review.

21 DR. PESCATELLO: Good. We then -- we spent some
22 time talking about the very 60,000 feet issues about the
23 overall funding, state funding of biomedical research in
24 the state and is there an opportunity, would there be

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1 efficiencies, would there be more dollars for research
2 with some kind of consolidation of the oversight of these
3 various biomedical research programs, including stem cell
4 research.

5 And that led into a discussion about
6 essentially a Phase II strategic plan that the Connecticut
7 Academy of Sciences and Engineering have done a Phase I
8 and we will be having them, Rick Strauss from CASE come
9 before our committee in a few weeks to talk that through.

10 We'll come back with a recommendation on that.

11 And then I guess finally the issue that I
12 brought up briefly before of better understanding going
13 forward for this Committee and for everybody involved in
14 the process, a better understanding of the research
15 projects that we approved. And importantly the progress of
16 the research projects that we've approved. And so perhaps
17 you want to discuss that here a little bit that we -- I
18 think we concluded two things.

19 First to on a regular basis, on an on-going
20 basis to have one or two or some subset of the outstanding
21 research projects investigators come before this Committee
22 and make a brief, but more substantive than just a tag
23 line, explanation of what their research is about and
24 where it stands. Again, for this Committee so that will

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1 be a part of the agenda for each of these meetings.

2 And then separately to have perhaps like an
3 annual one day event, public event, where the
4 investigators would make a presentation of what I think we
5 would call from our subcommittee something for the
6 sophisticated layman. It would be for everybody, but it
7 would be sophisticated enough and detailed enough that a
8 sophisticated layman could get a good sense of what the
9 research is all about and the progress made so far. And I
10 guess those last two things would obviously be something
11 this Committee would have to discuss and agree to do.

12 And that's essentially what the strategic
13 planning committee has been up to.

14 MR. WOLLSCHLAGER: Are there comments about
15 Paul's remarks? Specifically any thoughts about bringing
16 folks in on a regular basis?

17 DR. WALLACK: I would endorse that
18 recommendation. And I view that as Paul indicated as a
19 good opportunity almost like continuing education. A
20 continuing update in the field of stem cell research as it
21 pertains to what's going on in the State of Connecticut.
22 I think that the intent here is to ground us even better
23 in all of the aspects of what's going on. So I would
24 totally endorse carving out a 15 minute piece of something

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1 like that for a selected number of people at selected
2 meetings to come in and give that presentation.

3 DR. PESCATELLO: I mean I think realistically it
4 would take a half an hour.

5 MR. WOLLSCHLAGER: If I can, Paul, I think
6 there was also some discussion that that might also help
7 the sustainability of this Committee. That perhaps you'd
8 be more consistent attendance by appointed members if they
9 knew that there was a clinical or a scientific
10 presentation associated with each of the meetings.

11 DR. PESCATELLO: Yes.

12 MR. WOLLSCHLAGER: Other comments? Bob.

13 MR. MANDELKERN: I think it's an excellent
14 suggestion and I support it wholeheartedly.

15 DR. PESCATELLO: And the annual event for
16 the public?

17 DR. WALLACK: I would endorse the annual
18 event for the public as well because that would distribute
19 as we're doing here at this table to a wider audience not
20 just -- well, the public meaning the advocacy groups, the
21 media, whatever politicians we could grab into, whatever
22 it may be as far as the public.

23 DR. FISHBONE: I think it's an excellent
24 presentation and very good suggestions about what we

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1 should do. The one question that I would have is what are
2 the financial aspects of, a, having CASE do the
3 recommendations for us. And also of having the one day
4 meeting, do we have the money to support both of those
5 things?

6 MR. WOLLSCHLAGER: We have the money to
7 support one of those things.

8 DR. WALLACK: Well, the one day meeting I
9 don't think is a problem to support.

10 MR. WOLLSCHLAGER: Right.

11 DR. WALLACK: The CASE piece of it is a
12 significant in some -- somewhere between 70 and 90,000
13 dollars. So that's a significant amount of money.

14 MR. MANDELKERN: I thought we were talking
15 originally about presentations at our committee meetings
16 and one public. Now, we've jumped to CASE.

17 DR. WALLACK: No, no, that's two different
18 discussions.

19 DR. PESCATELLO: That's really to come --

20 MR. MANDELKERN: -- the CASE discussion is
21 a completely different one.

22 DR. PESCATELLO: The strategic planning
23 committee, at a future meeting of this Committee will make
24 our recommendation. We'll report on what CASE is proposing

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1 and we'll also, in our subcommittee, think through the
2 cost.

3 MR. WOLLSCHLAGER: I guess for this body
4 the question is if there is interest do you want CI/DPH to
5 start figuring out some logistics? How would we get people
6 in here. I will say for those of you who were here when
7 you guys asked the core to come in, I did talk to both
8 Renee and Hiphen after those meetings maybe thinking that
9 they might be saying, well, geez that was inconvenient or
10 what have you. Both of them said, separately by the way,
11 that they found it a good opportunity to sort of get a
12 chance to market in the form of members of this Committee
13 about what they were doing. So I think that it was well
14 received. It wasn't seen as a burden.

15 DR. WALLACK: I would move that we accept
16 the premise, the idea of bringing in a speaker involved in
17 the research at periodic meetings for a half an hour or so
18 presentation.

19 MR. WOLLSCHLAGER: Is there a second?
20 Second on that?

21 DR. FISHBONE: I'm just not sure of what
22 the protocol should be. Should we wait for the formal
23 report and recommendation or --

24 DR. PESCATELLO: -- that's a separate

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1 issue.

2 DR. FISHBONE: A separate thing.

3 DR. PESCATELLO: the CASE -- and it doesn't
4 have to be CASE. I mean we're going to listen to CASE and
5 talk about this whole idea of strategic planning.

6 DR. FISHBONE: Then I would second the
7 motion.

8 DR. PESCATELLO: This is just, you know,
9 for this is something -- just to help us to understand the
10 research on --

11 MR. WOLLSCHLAGER: -- and we might just
12 take it back to the subcommittee to figure out some
13 logistical arrangements.

14 DR. PESCATELLO: Sure.

15 DR. FISHBONE: So for both things.

16 DR. PESCATELLO: The subcommittee to work
17 on the bringing researchers before this Committee and also
18 organizing some kind of day long or longer thing for the
19 public.

20 CHAIRMAN GALVIN: Okay? Are we clear on
21 that? Any further comment? Moved and seconded. Any
22 further comment? All in favor of the motion, please, say
23 aye?

24 ALL VOICES: Aye.

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1 CHAIRMAN GALVIN: Any objections? The
2 motion is carried.

3 Are we at the public comment?

4 MS. HORN: We are.

5 CHAIRMAN GALVIN: Okay. I have one
6 statement I need to make after public comment. So do we
7 have any public comment?

8 DR. HISKES: I've had my say.

9 CHAIRMAN GALVIN: Okay, and very well said.
10 Let me just make a statement to all of you is that we are
11 in difficult budget times in Connecticut. There is a
12 large projected budget deficit largely due to personal
13 income tax, but it's also aided and abetted by people
14 conserving fuel, and not enough money being paid on gas
15 taxes. There is a scramble to identify funds. We are told
16 that the Department may face up to 10 million dollars in
17 revisions to the Health Department after the first of the
18 year.

19 We're also aware that this is not a time
20 for us to, if we have any new initiatives we can only do
21 those -- if we have the 200,000 dollar initiative we have
22 to show that we're going to cut back 200,00 dollars on
23 something else. So times are tough and getting tougher.

24 900,000 dollars, getting back to our

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1 earlier problem, sitting out there for 90 days probably
2 wouldn't sit out there for 90 days. It would probably end
3 up marching itself right back over and jumping into the
4 general fund.

5 So part of my being relatively hardnosed
6 and business like about this one issue is I can't leave
7 money hanging out there in the breeze or it will go right
8 back in the general fund. And if they do that the next
9 step is to say, well, you only spent 9.1 million last
10 year, we're only going to give you 9.1 million this year.
11 That is not impossible, but I don't want to even raise a
12 flag or get any introspection or a good hard look at that
13 by any of our friends in the legislative or administrative
14 branch because if they see unused money they're going to
15 pounce on it. And once it's been pounced you can forget
16 about it. It vanishes into the vast cavern of the general
17 fund and emerges as highways and computers for kids, and
18 this, that and the other thing, traffic lights in Wolcott,
19 whatever you ask.

20 So I'm trying to be realistic. I'm not
21 trying to be mean. I understand that people have problems.
22 A principal, individuals leave, plans fall through. I'm a
23 little concerned about Ann's remarks about how long it
24 took the process to boil up. I mean that's a lot of money,

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1 but I can't let it sit out there.

2 Thank you all very much.

3 DR. WALLACK: Are we finished?

4 CHAIRMAN GALVIN: Motion to adjourn. We are
5 adjourned.

6 (Whereupon, the meeting was adjourned at
7 3:05 p.m.)