1 field around a p-value of 0.05 is important. When
2 we start straying by 0.06, 0.07, something like
3 this, it may not be so important. But if most of
4 the p-values are reaching 0.1 or greater then we
5 have to reconsider the level of evidence.
6 Turning to the independent substantiation
7 from the 1996 trials, is allowed by FDAMA. In
8 oncology in particular there has been a guidance
9 written about uses other phases of the disease. In
10 this case it would be recurrent and newly diagnosed
11 and related populations. Again, judgment is
12 required in allowing this data to be brought
13 forward.
14 This slide summarizes some of the
15 strengths and weaknesses from our perspective.
16 It's not meant to be all-conclusive, but it's a
17 starting point. Among the strengths are that T-
18 301, the primary trial, was multicenter. The
19 control arm was a placebo wafer, which was an
20 attempt to control bias in terms of subsequent
21 interventions. The pathology review was pre-
22 specified and included a three-tiered process for
23 disagreement resolution.
24 We agreed with the primary endpoint of
25 survival. We also note that the point estimates of

1 the median survival trend in this trial and the
2 other trials is on the order of a two-month
3 benefit. And we did approve Gliadel in 1996, so
4 some degree of effectiveness has been conceded.
5 In terms of weaknesses, clearly the main
6 issue is whether the primary endpoint of survival
7 is statistically persuasive. Whether we ought to
8 be influenced by whether the primary analysis
9 should be unstratified, stratified by a log-rank,
10 whether there were multiple tests to determine
11 this, whether there ought to therefore be
12 adjustments for multiplicity, and whether the
13 increase in the sample size at the end constituted
14 an interim look.
15 Furthermore, from the clinical standpoint,
16 the benefit of two months is a modest benefit and
17 will need to be weighed against the risk and
18 against any possible imbalances including in the
19 favorable histology arm where there was a slight
20 imbalance in favor of Gliadel as in the
21 Scandinavian trial.
22 The assumption from the previous approval
23 was the glioblastoma multiforme subgroup was more
24 sensitive. It was also assumed that this would be
25 a bridging population in the T-301 trial. The GBM

1 population non-stratified was not statistically
2 persuasive at 0.2. And if we turn to the prior
3 approvals, to extend the diagnosis to the intend to
4 treat population, all malignant glioma, those
5 analyses were also non-significant.
6 You've heard about the North American and
7 Scandinavian trial and I'll just spend not too much
8 time on it -- a little bit of time. The intent to
9 treat population in the North American trial
10 included, the majority were glioblastoma multiforme
11 patients; 65 percent have that diagnosis, 35
12 percent had a more favorable histology, and they
13 were distributed evenly across the arms.
14 This is a summary of the survival results
15 from the study. As I mentioned, the protocol
16 statistical plan did not have a primary analysis.
17 It mentioned median survival as well as six month
18 survival would be analyzed, and they would be
19 analyzed by a log-rank as well as a Wilcoxin test.
20 The first column presents the results in
21 the intent to treat population, and the four p-
22 values are shown. The one presented is the p-value
23 of 0.06, but they also ranged in the overall
24 survival to 0.2, or 0.3 rounding off, and 0.1. The
25 glioblastoma multiforme arm we were persuaded

1 showed a survival advantage because of the four
2 analyses three showed a consistent trend. For this
3 reason it was approved in this population. We do
4 note that the point estimates of the median showed
5 a two-month benefit in favor of Gliadel.
6 Since we are being asked to consider
7 extending the indication to all patients with
8 malignant glioma, this slide attempts to place the
9 data for that larger population together, the North
10 American trial, the primary trial serving as
11 registration in 1996 and T-301. Approximately a
12 two-month difference, and the p-values are
13 presented and we will ask for your judgment on
14 whether these are confirmatory.
15 The other potential supportive trial, the
16 Scandinavian trial, you have also heard many times
17 today. I will show this summary slide. Median
18 survival, not six-month survival, was the primary
19 endpoint here. Thirty-two patients were entered
20 because of lack of drug supply. Of those 32
21 patients, 27 patients had glioblastoma multiforme.
22 All five patients who did not, who had the more
23 favorable histology, randomized to Gliadel arm.
24 Furthermore, the p-value was not adjusted for an
25 early analysis, and on this basis ODAC before felt

1 that the most that this trial could do was serve as
2 supportive.
3 This is my final slide before we turn to
4 the questions and listen to your comments. The
5 review issues that presented themselves to us can
6 be roughly summarized in three categories: the
7 level of evidence of the primary trial; the
8 evidence of drug effectiveness, particularly in the
9 primary endpoint of survival. I won't go over that
10 again. When we have a single trial we do like to
11 turn to secondary endpoints, whether any of the
12 secondary endpoints can serve to validate the
13 benefit.
14 If the committee feels strongly that a
15 log-rank analysis is valid when stratified by
16 country, we would like to hear comments on the
17 clinical meaning of this for the United States.
18 Since 12 patients of the 240 were entered in this
19 country, we would like to hear the implications.
20 The other category is whether the 1996
21 trials were confirmatory. And lastly, if T-301 is
22 considered a positive trial in conjunction with the
23 confirmatory trials, is the risk-benefit ratio
24 acceptable for an extended indication?
25 With that I will turn to the questions.

1 We'll be happy to answer any questions.

2 DR. NERENSTONE: Thank you, Dr. Martin.

3 We'll open it up for the committee to questions for

4 FDA, again perhaps waiting for discussion until

5 after the questions have been answered. Dr.

6 Rubenstein?

7 **Questions from the Committee**

8 MR. RUBENSTEIN: This question is for Dr.

9 Martin. Was it your understanding or was the

10 primary question that the trial was designed to

11 answer prospectively supposed to be restricted to

12 the GBM subgroup, or was it supposed to be for all

13 malignant gliomas?

14 Now you said that there was some argument

15 back and forth and that the FDA finally conceded

16 that you really couldn't define the GBM subgroup

17 preoperatively. It had to be defined

18 postoperatively. But that wouldn't prevent you

19 from arguing that the primary question was still

20 the GBM question. Was that your understanding,

21 that that was the primary question, and not for

22 malignant glioma overall?

23 DR. MARTIN: There is some ambiguity here

24 so I don't want to oversimplify. Yes, it was the

25 understanding that GBM was the population of

1 interest. However, we accepted the intent to treat
2 population as the primary population.
3 MR. RUBENSTEIN: So in other words, it was
4 agreed that -- there was no multiple comparisons
5 problem here. It was agreed at the outset that the
6 primary question was malignant glioma, not GBM?
7 DR. MARTIN: Yes.
8 DR. NERENSTONE: Other questions?
9 MR. RUBENSTEIN: Yes, I had some further
10 questions for Dr. Li. You argued that the p-values
11 should be adjusted upward because of the fact that
12 there was an interim increase in sample size from
13 200 to 240.
14 DR. LI: Yes.
15 MR. RUBENSTEIN: But was that interim
16 increase in sample size associated with an actual
17 interim look at the data, or was it dictated
18 without looking at the data?
19 DR. LI: We don't know exactly what
20 happened when the sponsor decided to increase the
21 sample size. The sponsor submitted an amendment to
22 the protocol and they mentioned that because the
23 safety monitoring committee suggested them to do
24 so. But I believe someone did look at the data
25 before they make the decision.

1 MR. RUBENSTEIN: But do you know that
2 somebody looked at the data? Was it written
3 somewhere that somebody looked at the data?
4 DR. LI: No.
5 MR. RUBENSTEIN: Let me ask another
6 question then. Let's assume for a moment
7 hypothetically that nobody did look at the data.
8 That the sample size was increased without looking
9 at the data. Would you feel that that necessitated
10 increasing the p-value upward?
11 DR. LI: If there is no interim look at
12 all and you judge that the sample size is
13 insufficient to do something -- some other reasons
14 rather than look at either blind or unblind data,
15 then you don't have to do any upward adjustment.
16 Otherwise, no matter you -- and look at the unblind
17 data or the blind data, you still need some
18 adjustment because you already have some idea about
19 the data itself.
20 MR. RUBENSTEIN: So if in fact there was
21 no interim look then it wouldn't really be
22 necessary to upwardly --
23 DR. LI: Yes. That's why I say may result
24 in an upward adjustment.
25 MR. RUBENSTEIN: Second question. You

1 argued that doing the analysis stratified by
2 country, because that wasn't the pre-specified
3 analysis explicitly in the protocol, because they
4 hadn't said in the protocol, we will stratify the
5 analysis by country, you argued that that actually
6 would force you to upwardly adjust the p-value
7 also, because it introduces, I suppose, a multiple
8 comparisons problem.
9 But let me ask, if you take Dr.
10 Piantadosi's statement at face value, that in fact
11 this was the only analysis that he did, number one,
12 would you still believe -- if this was the only
13 analysis that he did would you still believe that
14 there was a multiple comparisons problem? And
15 secondly, would you take any issue with him that as
16 the only analysis this was an appropriate analysis
17 to do?
18 DR. LI: If -- and it's a big if -- if
19 there is no written document to support the non-
20 stratified log-rank test was designed as the
21 primary analysis, and Dr. Piantadosi did not even
22 think about the other analysis at all, and that's
23 his first and only pick, then I don't think you
24 need to do any other adjustment for this purpose.
25 But for the sample size increase probably you still

1 need to do the adjustment.

2 DR. TEMPLE: Can I --

3 DR. NERENSTONE: Dr. Temple?

4 DR. TEMPLE: We usually like to rely on

5 documented things. It's 2001, or it was 2002.

6 It's not unknown to people that you're supposed to

7 specify in some detail the precise analysis you're

8 going to do, and it's not unobvious that the one

9 that looks best is the one that stratifies by

10 country. So being slightly suspicious we wonder,

11 can it be documented in a certain way that that was

12 the only analysis done, that it was done before all

13 the data? It's not that we do or don't believe

14 people, but for goodness sakes, people know that

15 that's an issue by now. How come we have to guess?

16 MR. RUBENSTEIN: I won't argue with that.

17 DR. TEMPLE: But that's the theme. Of

18 course if it was all done completely kosher we

19 wouldn't worry. But that's why we're nervous,

20 because we're inclined that way.

21 MR. RUBENSTEIN: I wouldn't argue with

22 that. But wouldn't Dr. Li agree that when you

23 randomize in a stratified fashion, that you

24 generally would try to analyze as you've

25 stratified, except if you feel that the

1 randomization might introduce an over-
2 stratification with respect to the analysis, as
3 suggested by one of Dr. George's questions?
4 So in other words what I'm saying is,
5 wouldn't you agree that there's something different
6 about country as opposed to performance status,
7 age, and tumor type, because the randomization has
8 been stratified on country? It hasn't been
9 stratified on those other things.
10 DR. TEMPLE: No, it wasn't. That's not
11 what Steve said. He said that because you
12 stratified by site, you inevitably must have
13 stratified by country. It wasn't stratified by
14 country. They didn't randomize -- they randomized
15 by site, not be country. Now it turns out it's
16 also stratified by country since each site is
17 within a country. But that isn't what they did.
18 They didn't do that. They could have. They could
19 have assigned people in France, Germany, and all
20 that, and had a central randomization.
21 MR. RUBENSTEIN: No, but with all due
22 respect, it's obvious that when you stratify by
23 center you're also stratifying by country.
24 DR. TEMPLE: True. But if it's that
25 obvious and they intended to do it, it really would

1 have been better if they had said so. I'm not
2 saying what you should conclude, but these are not
3 unknown problems.
4 DR. LI: It's not necessary to do the
5 analysis according to what you stratify. For
6 example, you can stratify by several prognostic
7 factors like Karnofsky score, age, and whatever you
8 want. You could have several. But when you do the
9 analysis you can only -- you can do stratified
10 analysis or non-stratified analysis, as I said, as
11 long as you specify it in the protocol. If you
12 have 10 unstratified variables and you have about
13 30 in the strata there you still can do the non-
14 stratified analysis and get the result. We are not
15 saying we're not going to accept the result without
16 some analysis. That's not the point.
17 MR. RUBENSTEIN: I take your arguments. I
18 just think this issue really boils down to, was the
19 analysis done by Dr. Piantadosi reasonable? And do
20 you really need to talk about increasing -- let's
21 not browbeat this.
22 I have one final question for Dr. Shapiro.
23 I was really glad that you pointed out that they
24 hadn't censored on death when they did the
25 comparison of time to the various deficits.

1 Because what that suggests is that really all of
2 those differences that you're seeing in time to
3 deficit in personality, speech, visual status, et
4 cetera, KPS, that they're really driven by time to
5 death differences.
6 You said that you had redone the analysis.
7 How many of those p-values disappeared on you when
8 you took out -- when you used death as a censorship
9 variable as opposed to an event?
10 DR. LI: Let me answer the question
11 because I did the analysis. Only one has a p-value
12 of 0.01, which I believe is speech.
13 DR. NERENSTONE: Just point of
14 clarification. So the other p-values became non-
15 significant?
16 DR. LI: Became non-significant. Only
17 one, which is speech, 0.01.
18 DR. TEMPLE: By which you mean greater
19 than 0.05; is that what you mean?
20 DR. LI: The rest of the 10 measurements
21 are all above 0.21. The smallest one except speech
22 is greater than 0.21. So because death may be
23 caused by some other reasons, and the event, those
24 events may happen before death occurs and they did
25 not record it. So if you count death as an event

1 you are artificially prolonging the time to the
2 event. So that's why we believe death should not
3 be counted as an event.
4 DR. NERENSTONE: Mr. Ohye?
5 MR. OHYE: I have a question for Dr.
6 Martin. That refers to the amount of support the
7 sponsor can glean from the prior work. If the
8 present indication that they're applying was
9 narrowed, would then the prior clinical resource be
10 more supportive?
11 DR. MARTIN: Is your question, would it be
12 more supportive if the malignant glioma intend to
13 treat population were positive? Could you rephrase
14 the question, please?
15 MR. OHYE: No, the present indication that
16 they have is for --
17 DR. MARTIN: Recurrent glioblastoma
18 multiforme, yes.
19 MR. OHYE: Right. And the present
20 indication that they're asking for is broader in
21 terms of their claim. Now if they narrowed that
22 claim would the prior work be more supportive?
23 DR. MARTIN: If they narrow the claim to
24 just glioblastoma multiforme that are newly
25 diagnosed the p-value moves to somewhere around

1 0.2, so it would not be helpful.

2 DR. TEMPLE: So it might make the other

3 data seem more relevant but it makes the new data

4 not look so good.

5 MR. OHYE: Thank you.

6 DR. TEMPLE: But just as a general

7 comment. We've written about this extensively. I

8 think in the setting where we've already approved

9 one stage of the disease, one solid, reasonably

10 persuasive study at conventional levels of

11 significance would do the job. It's not like

12 relying on a single study where we'd say, you've

13 got to have a p-value that knocks your eyes out.

14 Just one more, because it's obviously a closely

15 related disease. So it really all turns on how

16 persuasive the 301 study is.

17 DR. NERENSTONE: Dr. Taylor?

18 DR. TAYLOR: I had a question about the

19 radiotherapy. You mentioned that only 78 and 80

20 percent of the patients received the prescribed

21 does of radiotherapy. Can you tell us why and what

22 the dose ranges were, since radiotherapy is the

23 only known and accepted treatment for GBM?

24 DR. SHAPIRO: I mentioned that 78 percent

25 of patients of Gliadel and 80 percent of patients

1 from placebo received standard regimen of radiation
2 therapy, which includes radiation therapy of total
3 dose of between 55 and 60 given between 14 and 28
4 days after the surgery, and also fractionated
5 within 30 to 33 fractions over the course. The
6 remaining of the patients either received no
7 radiation therapy for patients who had anaplastic
8 oligodendroglioma it was not included in the
9 protocol to receive radiation therapy.
10 Part of the patients received non-standard
11 radiation therapy which includes radiation therapy
12 given outside the timeframe or the total dose was
13 less than the determined dose. And delay in
14 radiation therapy can be caused by a patient's
15 condition which deteriorated at the time of the
16 scheduled radiation therapy, or lack of supply, or
17 patient was moved to a different institution for
18 this procedure.
19 DR. NERENSTONE: Dr. Albain?
20 DR. ALBAIN: To Dr. Li, I was just -- I'm
21 still a little confused by your use of the word
22 stratified and wondered -- at least for a
23 clinician, I thought when you use the word stratify
24 that means that up front the randomization process,
25 there was stratification for X, Y, or Z variable.

1 DR. LI: Correct.

2 DR. ALBAIN: But whereas you're using the
3 word stratified log-rank and adjusting for -- I
4 think you're adjusting, are you not, for factors
5 that may be prognostic variables? However, the
6 randomization process was not stratified for those
7 variables. Therefore, why isn't the multivariate
8 as shown to us reasonable evidence for a treatment
9 effect? You quoted Dr. Simon that p-values for
10 multivariate analyses were not interpretable.
11 That's exactly what you said. I wrote it down as
12 you spoke, and I was quite confused about that
13 because I thought that's the right way to do it
14 when you don't have up front use of that variable
15 as a stratification factor in the randomization
16 process. Are you using the word stratified to mean
17 adjusted? Is that how you --

18 DR. LI: Stratification is -- stratified
19 analysis is one kind of adjusted analysis.

20 DR. ALBAIN: But aren't you supposed to
21 use the variable, if it was used up front, to
22 stratify the patients so the arms are balanced, or
23 do I have the wrong statistical training here?

24 DR. TEMPLE: Sometimes you just stratify
25 to be sure the groups will be similar with respect

1 to men and women, or a particular diagnosis. You
2 may or may not then do a stratified analysis. We
3 accept either. We just want to know what it's
4 going to be.
5 DR. ALBAIN: You're doing a stratified
6 analysis when it was not ordained up front that the
7 arms would be balanced by those factors. So I
8 thought then, using a Cox model was the more
9 appropriate approach.
10 DR. LI: No matter if your randomization
11 was stratified or not for certain covariates, if
12 you believe the survival pattern -- that's not
13 accurate-- the survival pattern in the age above 60
14 and below 60 is below different, we said it's not
15 proportional hazard. Then in this case you should
16 use stratified Cox model to do the analysis because
17 you know that the survival pattern, your survival
18 whatever, hazard ratio is not proportional in terms
19 of the -- is not proportional, so you need to
20 stratify by this covariate.
21 So it's not necessarily due to the pre-
22 specified stratification to do the stratified
23 analysis.
24 DR. ALBAIN: But the investigators
25 presented a complete Cox model to us that had p-

1 values and hazard ratios. Whereas you are showing
2 independent adjusted p-values, which you just said
3 is Cox adjusted. So I'm becoming more confused
4 here about what type of analysis --
5 DR. NERENSTONE: Maybe Dr. George can shed
6 some light for us.
7 MR. GEORGE: I think what you're saying is
8 right. You are right to be confused, because of
9 the way it was presented. I think the answer is,
10 what you're used to seeing in randomized clinical
11 trials when they say randomization was stratified,
12 that's what they mean. But there's another use of
13 stratification in post-hoc ways, and basically it's
14 to adjust for various factors. You can do it by
15 the stratification technique, you can do it by
16 modeling of various kinds, and you can combine the
17 two. But they're all ways to adjust for these
18 factors.
19 But you're right I think, that usually you
20 see it in the literature, when you see somebody
21 says that, the language they're talking about,
22 randomization was stratified by this, then the
23 analysis usually refers to other things.
24 DR. ALBAIN: So is the Cox model as was
25 presented on whatever slide that was, an

1 appropriate way to look at the variables?

2 MR. GEORGE: My opinion is yes, but it's

3 not the way you put it. You said it was the

4 preferred way or the only way or something, the

5 best way or something.

6 DR. ALBAIN: No, he quoted Simon as saying

7 it was uninterpretable.

8 MR. GEORGE: No, I'm sure what Rick said

9 was, you have trouble trusting these p-values when

10 you're using step-wise procedures for selecting the

11 variables. I'm sure that's what he said. Not that

12 --

13 DR. TEMPLE: He only referred to the step-

14 wise procedure.

15 DR. LI: As far as step-wise selection.

16 MR. GEORGE: It was the procedure for

17 selecting the variables. It wasn't the technique

18 itself.

19 DR. TEMPLE: Let's be clear on this.

20 We're not saying that one or another analysis is

21 never okay, or is better than the other, is worse

22 than the other. The only issue we're talking about

23 is whether people did a lot of analyses and might

24 have picked the best one, because that poses its

25 own problems. I'm sure Dr. George will agree with

1 that. You can't just do 20 analyses and pick the
2 one that comes out best. You're supposed to
3 specified. And one question is how specified these
4 analyses actually were.
5 DR. NERENSTONE: Dr. Moye?
6 DR. MOYE: This deals with the first
7 question that Dr. Rubenstein asked and Dr. Li
8 responded to in terms of whether there should be a
9 type one error inflation because of the interim
10 increase in sample size. I appreciate, Dr. Li,
11 your requirement for having documentation that in
12 fact there was no review of efficacy data. But if
13 I understood you correctly, we really need to have
14 some documentation to be assured that there wasn't
15 a look at efficacy data, which of course is going
16 to have type one error complications.
17 In my packet there appears to be such
18 documentation. As I read this data, apparently the
19 interim review was an examination of event rates in
20 one group, but not an examination of event rates in
21 both groups, and that Dr. Chien, the statistician
22 felt that that was an adequate response to his
23 question about type one error inflation. Just as a
24 clarification.
25 DR. NERENSTONE: Would you come to the

1 microphone and identify yourself?

2 MR. TRAN: I'm Gon Tran, statistical team

3 leader, FDA. Actually I think the sponsor

4 submitted that package to us. I reviewed that

5 package and I sent back two comments. The second

6 comment was regarding the sample size, the increase

7 of sample size. So my comments, actually I asked

8 the sponsor, we asked the sponsor to provide all

9 those meeting minutes and details of the data

10 safety monitoring, actually what you have done.

11 Then the last sentence in my comment I said,

12 otherwise the type one error should be adjusted.

13 We needed to know the details, what you

14 have done. If you looked at the data, you looked

15 at any type of comparison, details of the data, you

16 have to adjust for type one error. That's the

17 comments we sent to the sponsor.

18 DR. MOYE: If I could respond. There's a

19 very brief memo here dated April 15th in which they

20 say the sponsor's response to statistical comments

21 in a previous stat review is acceptable. The

22 reviewer does not have any further comments on the

23 amendment of the protocol. So I just took that to

24 mean that the issue had been resolved. Am I wrong?

25 MR. TRAN: You are right. Then they sent

1 a couple of pages to us, and from those pages, as
2 you said, I believe -- I don't remember the
3 details, but I believe I looked at those details
4 and we accepted whatever response to us.
5 DR. MOYE: So I guess to finish this off,
6 apparently then there is no issue about a further
7 type one upward adjustment of the type one error
8 for the sample size issue. That essentially has
9 been resolved and no such upward adjustment is
10 necessary. Is that a correct conclusion?
11 MR. TRAN: I agree.
12 DR. NERENSTONE: Other questions for FDA?
13 Okay, then what I'd like to do is open it
14 up for discussion for the panel members. Dr.
15 Taylor, would you like to lead us off?
16 **ODAC Discussants**
17 DR. TAYLOR: Yes. I think I'm totally
18 confused on some of the statistics. I had some
19 concerns that were clinical. One is I am a little
20 concerned about making a decision about country
21 versus center when we really don't know the
22 differences in how those are treated, and we don't
23 know -- I don't feel comfortable in saying that
24 those centers treat brain tumors the same way that
25 the centers in the United States treat brain

1 tumors.

2 As it was already alluded to, they have an
3 age cutoff that's different. We've already talked
4 about with Dr. Fine that they had a difference in
5 radiotherapy dose, and I'm not sure that we can
6 extrapolate this data to a population that may be
7 older, may get much higher doses of radiotherapy,
8 that we may see a difference in the toxicity.

9 In terms of the confirmatory data for
10 other endpoints such as quality of life I was
11 somewhat discouraged by the lack of objectivity in
12 determining those features. And certainly with the
13 analysis without deaths, we don't have them
14 confirming the results anyway.

15 DR. NERENSTONE: Dr. Buckner, do you have
16 some comments?

17 DR. BUCKNER: Partly to come back to
18 issues that have been raised before, but to
19 emphasize my questions. One is about the
20 generalizability of the data, similar to Dr.
21 Taylor's comments, in that only patients that were
22 less than 65 with unifocal lesions not crossing the
23 midline or going to the ventricle that are at least
24 partially resectable in order to implant the wafers
25 are included in the study population. So I think

1 those eligibility criteria -- not unusual for
2 clinical trials, but I think they do limit the
3 generalizability of the data for the overall
4 population of all patients with malignant gliomas.
5 Second of all I have some concerns about
6 the lack of disclosure of pathology review data.
7 Specifically, central pathology review data were
8 not disclosed at this meeting. However, having
9 been here in Washington for much longer than I had
10 anticipated on September 11th, I had time to look
11 at the previous briefing document prepared by the
12 sponsor, and those data were included in that
13 document. They are not included in the one that
14 was prepared here.
15 We have acknowledged already that
16 histology is a powerful prognostic variable. By my
17 recollection -- and I will acknowledge my
18 recollection is not perfect. By my recollection
19 however, from those data in the central pathology
20 review compared with the final pathology review,
21 there were less patients with glioblastoma
22 multiforme in either of the treatment arms, there
23 were more patients with oligodendroglial containing
24 tumors in both arms, and there was greater
25 imbalance in the number of different patients

1 between the Gliadel arm and the placebo arm, and
2 the histology factors favored the Gliadel arm.
3 I think those are relevant data for this
4 group to review, and I think it's unfortunate that
5 we do not have them to review. Personally, I
6 believe the relevant comparator is not the local
7 pathologist who may or may not be an expert
8 neuropathologist or even a neuropathologist at all.
9 The relevant comparator is between the experts.
10 That is, the person that does the central pathology
11 review compared to the final pathology review.
12 Now is that relevant -- how might this be
13 relevant in this trial? The differences in the
14 intent to treat population by anyone's estimate in
15 the randomized trial. Since histology is a strong
16 predictor of survival, I believe it is reasonable
17 to ask that the data by analyzed by both the
18 central and final pathology review. If by the
19 central pathology review the data are strengthened,
20 then that would substantially increase the
21 rationale for approving the new indication. On the
22 other hand, if they go in the opposite direction,
23 then I think that could provide some clarity to the
24 situation.
25 Furthermore, I think it emphasizes the

1 importance of the multivariate analyses. If one of
2 the variables in the multivariate analysis may be
3 in question, then it really begs the question of,
4 regardless of what statistical techniques are used,
5 or whether we set p.03 or p.07 as the cutoff, those
6 analyses are only designed to look at random
7 differences in populations, not non-random or
8 intentional or non-intentional but differences in
9 the two study populations that are non-random.
10 I am bothered that depending on the
11 technique that one uses in a multivariate analysis
12 one gets different answers. Personally, I do not
13 think that -- I think with the differences in
14 prognostic variables, the only reliable analysis
15 that I would hang my hat on scientifically, or even
16 as a clinician, is the multivariate analysis.
17 That's all I have to say.
18 DR. NERENSTONE: Dr. George?
19 MR. GEORGE: I just wanted to summarize
20 what I'm making of all this. I'm a little
21 disturbed by the pathology too, only because of Dr.
22 Buckner's comments. But in overview, my take on
23 this is that this is a well-designed, well-
24 executed, well-analyzed study with two defects; one
25 minor and one major. The minor one -- both of

1 which led to some of our conundrums here.

2 The minor one is the ambiguity in the

3 statistical analysis plan, and the way it was

4 conveyed, and the way this evolved. I say that's

5 minor compared to the major one which is that the

6 study was too small. Could have been anticipated

7 to be too small from the beginning, I think. But

8 too late to do anything about that one. Too late

9 to do anything about either one of them actually.

10 My judgment is that it should have been

11 about somewhere between 50 percent to 200 percent

12 larger to definitively get at some of these things.

13 It wasn't designed this way, but if you just looked

14 at it, the hazard ratio of about 1.6 would have

15 produced about this size of sample size. In the

16 previous study the hazard ratio was about 1.3 and

17 it was in this study too. That's the converse of

18 the 0.7-something we were looking at. So it could

19 have been designed to take that into account I

20 think. But anyway, that's water under the bridge.

21 The results themselves I think are -- what

22 is impressive to me is how consistent they are with

23 previous results, particularly in the recurrent

24 disease area. But because of these other things,

25 the evidence or the strength of evidence is kind of

1 borderline; not strong. That puts me solidly on
2 the fence. But I think -- that will help you a
3 lot. The consistency issue is an important one for
4 me and that part is pretty impressive.
5 DR. NERENSTONE: Dr. Kelsen?
6 DR. KELSEN: When we're dealing with a
7 study in which benefit might be modest, and I think
8 that's the essence of Dr. George's point which I
9 agree upon, I guess risk becomes much more
10 substantial to me anyway. So I have a question for
11 the experts on the panel.
12 There's a lot of concern about the fact
13 that older patients were not included into this
14 trial. I don't know how much experience there is
15 in the currently approved indication, that is for
16 recurrent disease in which patients receive Gliadel
17 wafers. Is the risk in older patients who have
18 already -- do we have data in the risk in treating
19 older patients with Gliadel wafers for the already
20 approved indication to say it's safe to do in that
21 population? Or is the risk not known, or is the
22 risk very high in that population and we should be
23 very concerned?
24 DR. NERENSTONE: Dr. Buckner?
25 DR. BUCKNER: I don't have an answer to

1 that question.

2 DR. KELSEN: Does the sponsor have an

3 answer? Is it legitimate to ask the sponsor if

4 they have a -- okay, does the sponsor have an

5 answer to that question? You said there were 6,000

6 patients who have gotten -- I think you said there

7 were 6,000 patients who have received this

8 treatment. Do you have any post-marketing data on

9 the risks of doing this in older patients in the

10 United States?

11 DR. BREM: From our experience at Hopkins

12 and multiple centers, Mass General, so on that are

13 using this routinely, it's actually used quite

14 routinely in older patients because in those

15 patients systemic chemotherapy is deemed quite

16 risky, and since they're undergoing craniotomies

17 for tumor debulking it's considered the most

18 reasonable way to deliver the adjuvant therapies.

19 So in fact there's quite extensive experience and

20 we've seen no increased risk whatsoever in our

21 experience with that.

22 DR. BUCKNER: There is a related issue of

23 age that confused me even more. In the

24 multivariate analysis in patients with glioblastoma

25 provided by the sponsor age was not a significant

1 prognostic variable. That's at marked variance
2 with most of the existing literature, suggesting
3 that there's either something funny about the
4 analysis or that there's some interaction between
5 treatment and age that's not fully disclosed.
6 Similarly, in the multivariate analysis
7 for the overall intent to treat population
8 glioblastoma as a distinct histology was not
9 considered to be a prognostic variable. That also
10 is at variance with the bulk of the literature.
11 Why is that? Again, either there's something funny
12 about the analysis or the patient population that
13 was selected, or the definition of glioblastoma,
14 which I've alluded to already, or some interaction
15 between histology and treatment that has not been
16 explained.
17 So I have some questions, again sort of a
18 roundabout way of getting to the age issue.
19 DR. NERENSTONE: Dr. Fine?
20 DR. FINE: I think the most important
21 thing to understand about age in this disease is
22 that although the cutoff is arbitrary, I think most
23 of us who take care of this disease appreciate the
24 fact that patients over the age of at least 70 who
25 develop this disease have a particularly virulent

1 course with survivals that are significantly worse
2 than what you saw, to the point that there are many
3 physicians across the country who advise patients
4 or families not to even treat with radiotherapy for
5 this group.
6 And there is now genetic evidence -- part
7 of the confusion with what Dr. Buckner's talking
8 about, about the histology, it's going to go
9 further than that because we know that glioblastoma
10 probably is not a single disease. We know
11 genetically it's at least two different diseases
12 that may have very different responsiveness to
13 alkalating agents. And the subgroup of patients
14 over the age of 70 have one particular genetic
15 phenotype that is certainly more refractory to
16 treatment.
17 So whatever we say about age, we have to
18 realize we're dealing with probably a different
19 disease, at least a higher percentage of patients
20 with this disease in that age group.
21 DR. NERENSTONE: I guess I would just like
22 to make a comment as a non-statistician, and I'm
23 very glad to hear everyone else is as confused as I
24 am. But I'm very concerned that we have perhaps an
25 intervention that has a borderline significant

1 ability to prolong survival but no supportive
2 documentation clinically that says that that is
3 meaningful and questions about the statistics even
4 underlying this whole thing. I'm very concerned
5 that we're really going to approve a placebo.
6 So I'm, again, as perplexed as some of the
7 rest of you as to which way to go on this, so I'd
8 like some more help.
9 Dr. Sledge?
10 DR. SLEDGE: I don't think it's a question
11 about us approving a placebo. This is not a new
12 drug. This is a drug that was approved by this
13 committee on the basis of a survival advantage in a
14 more advanced group of patients than what we're
15 talking about today. So I don't think we're
16 talking about a placebo.
17 What we've heard today, this is -- you
18 know, whenever statisticians duel, innocent
19 bystanders die of boredom.
20 [Laughter.]
21 DR. SLEDGE: The question here I think is,
22 how consistent is this with the previous trials? I
23 must say, while I consider this trial weak based on
24 it being underpowered, it certainly appears to me
25 to be consistent with the other data that we've

1 got.

2 DR. BUCKNER: For the newly diagnosed

3 patients, Dr. Sledge, again there were -- a third

4 of the patients in the Gliadel group had better

5 prognosis, or roughly a third. Five-sixteenths is

6 not quite a third, I recognize that. Had a better

7 prognosis than the patients in the placebo arm.

8 There were some questions raised at the time when

9 this drug was approved in the recurrent glioma

10 setting also about imbalances in the two arms.

11 So yes, the data are consistent, but so

12 are the problems in the trial interpretation. Not

13 the trial design, but actually in the data

14 analysis.

15 DR. NERENSTONE: So just to clarify, Dr.

16 Buckner, you feel that perhaps this borderline two-

17 month improvement in survival could actually be the

18 natural history of better histology on the Gliadel

19 arm that's not accounted for or not discussed by

20 the sponsor? Or that's your concern.

21 DR. BUCKNER: Exactly. I would very much

22 -- all of us would like to find a truly effective

23 treatment. That is not -- and I think it's one

24 that has very low risk, but it's not no risk and

25 it's not no cost. A slightly risky, costly,

1 ineffective therapy is not a step forward.

2 DR. NERENSTONE: Dr. Carpenter?

3 DR. CARPENTER: Is there anything we've

4 heard so far -- maybe the FDA reviewers could

5 comment. There's a lot of discussion about the

6 fact the study is probably underpowered and that

7 depending on the method of analysis whether there's

8 a significant difference in outcomes is arguable.

9 Yet the direction of the effect -- the way I read

10 this, the direction of the effect is favorable in

11 every single analysis that was done in favor of the

12 wafer. Is that accurate?

13 DR. BUCKNER: The difference is the same;

14 the difference. But the question is, is it

15 attributable to the wafer or not? Is it

16 attributable to the drug or not? That's the real

17 question.

18 DR. CARPENTER: And a multivariate

19 analysis at least approaches that, although it may

20 not answer it to your satisfaction.

21 DR. BUCKNER: We're getting into p-values

22 above 0.1.

23 DR. NERENSTONE: Dr. Temple?

24 DR. TEMPLE: Lots of studies lean, but

25 it's conventional to apply a certain test for

1 statistical significance that you hope takes care
2 of minor variations that occur as a result of
3 randomization. So we wouldn't be here if it wasn't
4 trending favorably, if there wasn't some colorable
5 way to say there might be something. The question
6 is, does it pass some ill-defined threshold?
7 Alison -- I'm sorry to do this -- we were
8 talking about the possible effect of differences in
9 how favorable histopathology was. Obviously when
10 your p-values are all hovering about 0.05, any kind
11 of imbalance, even of a modest number of patients,
12 can be the explanation of why it goes one way or
13 another. There was a concern and you may want to
14 address that, Alison.
15 DR. MARTIN: I'll start out and then let
16 Dr. Li take over.
17 DR. NERENSTONE: Speak into the
18 microphone.
19 DR. MARTIN: I'll start. In our tumor
20 histology slide we showed that there were more
21 favorable histologies in the Gliadel arm, as you
22 said, Dr. Buckner. The category that had the
23 greatest degree of imbalance was the anaplastic
24 oligoastrocytomas, which was eight in the Gliadel
25 arm and three in the other. So we did an

1 exploratory analysis, Dr. Li did actually, to look
2 at the impact of that particular histology. Maybe
3 he can address that.
4 DR. LI: First of all I'd like to say it's
5 an exploratory analysis and it's not pre-specified,
6 and it's after the fact. After we see there is an
7 imbalance between the two subgroups of the non-GBM,
8 there is eight versus three AOA patients. Eight
9 patients in the Gliadel group and three patients in
10 the placebo group. So after we remove -- taking
11 those 11 patients out from the analysis dataset we
12 get the p-value for the treatment effect. That's
13 the 0.18, which is a non-stratified analysis, non-
14 stratified by country. If we use the exact same
15 dataset we got a p-value of 0.09, which is
16 stratified by country analysis. The log-rank is
17 stratified by country, exactly what the sponsor
18 did.
19 So it looks like -- it's purely an
20 exploratory analysis, and it's kind of post-hoc.
21 Looks like the result is driven by these better,
22 favorable subgroups of the non-GBM patients. This
23 kind of imbalance is --
24 DR. TEMPLE: Which could explain the
25 surprising analysis that the ITT analysis is more

1 favorable than the glioblastoma multiforme
2 analysis, which was the more favorable outcome,
3 remember, on the previous study. But again, you
4 can do anything with data. We don't let other
5 people do this, but we occasionally do it
6 ourselves.
7 DR. NERENSTONE: Dr. Kelsen?
8 DR. KELSEN: Just a question the FDA might
9 help me with and just to clarify what I asked
10 before. Do you have any serious concerns that the
11 toxicity from the -- in the Gliadel arm is
12 substantially greater than in the placebo arm?
13 That is, in your analysis of risk of side effects,
14 do you believe that the patients were put at risk
15 who receive Gliadel compared to patients who
16 randomized the placebo wafer? Understanding that
17 you had some concerns about the wafer remaining in
18 place.
19 DR. SHAPIRO: When we assessed the deaths,
20 post-operative deaths we found that there were
21 three patients on the Gliadel arm who died in the
22 first 30 days from cerebral hemorrhages on Gliadel
23 arm, and there were no deaths for this particular
24 reason in the placebo arm. The rest of the
25 complication, of the local complications appear to

1 be balanced in both arms with the exception of what
2 the sponsor and we agreed on, increased
3 intracranial hypertension and CSF leaks.
4 DR. NERENSTONE: Mr. Lustig?
5 MR. LUSTIG: Understanding that it's late,
6 but a couple of comments. No one is more confused
7 than I am around this table, but I'm doing my best
8 here. For me this decision, I don't know that
9 there's certainly anyone around this table for whom
10 this decision is more difficult. I really struggle
11 with this.
12 I'd like to tell you that I think that the
13 role of the patient representative, despite
14 comments from Dr. Friedman, is not to be either
15 visceral or emotional but to try to perhaps look at
16 things in the big picture, take into account my own
17 experience and those other people that I know that
18 have lived and suffered through brain tumors, and
19 in particular GBMs.
20 I don't doubt the commitment or sincerity
21 of the investigators and of the sponsor. I
22 understand the struggles of this disease from a
23 research standpoint, the small numbers, the
24 intensity of the disease, the complications. I
25 guess a couple of comments related to this whole

1 discussion and trying to -- and this idea that
2 we're maybe a little bit of borderline.
3 From my experience, I learned that
4 medicine is far more an art than a science, and
5 especially when it comes to brain tumors. So I
6 think we do need to allow for something in that
7 discussion. With all respect, I don't think we can
8 necessarily apply the same kinds of rigor, if you
9 will, to our discussions of a study like this that
10 we would to other cancers or other diseases. So I
11 do think there's got to be some flexibility.
12 That all being said, I'm still very -- I
13 guess perhaps out of turn here I would only, or
14 perhaps inappropriately I would suggest that
15 there's a lesson to be learned here, whatever the
16 final advice is coming from the committee, which is
17 that both from the sponsor's side and from the
18 agency's side these studies need to be -- because
19 this is not the first one I've sat in on where
20 there's been a real struggle and a real question.
21 Things have been very fuzzy. There's a real need
22 to do a better job, I think, and take the time and
23 effort to build the studies in such a way, whether
24 it be around getting the right numbers or
25 specifying the right measurements, in order to try

1 to get clearer outcomes.

2 I don't know, but it seems to me that this

3 is not a single example of a problem where, as Dr.

4 George said, it's easy to just sit on the fence.

5 DR. NERENSTONE: Other comments? Dr.

6 Blayney?

7 DR. BLAYNEY: At the risk of having to

8 vote first because you may start at this end of the

9 room, I'd like to explain what I'm going to vote.

10 I have changed my mind four different times in the

11 last two weeks on this issue.

12 I think, as everyone has said, this is a

13 marginal study. I will accept at face value the

14 presentation by the sponsor that while not strictly

15 adhering to the documentation requirements and the

16 keeping of minutes, I will accept their statement

17 that their analysis, which to me makes some sense,

18 that given the small numbers of patients per

19 country that the analysis by country makes some

20 sense and that's the one they did.

21 The benefit is marginal. I'm persuaded by

22 the meta-analysis format that I see that the

23 results seem to be consistent. And I accept Dr.

24 Buckner's argument that the histologic may be in

25 favor in both studies. That's what neurosurgeons

1 have to deal with, the pathologic uncertainty when
2 they implant these things.
3 So given all that and the fact that I hope
4 we're going to make better strides in the next few
5 years and get better treatments, I'm going to vote
6 in favor of this for all those reasons.
7 DR. NERENSTONE: Maybe we should then turn
8 to the questions. I'm going to skip the entire
9 first page and go right to the questions. Is study
10 number T-301 an adequate and well-controlled trial?
11 Are we allowed to break that down into two
12 separate, whether it's well-controlled and whether
13 it's adequate? Let's start first, is it well-
14 controlled? Comments?
15 DR. BUCKNER: Despite my previous
16 comments, I do think it is a well-controlled trial.
17 DR. BRAWLEY: I would agree. I think it
18 shows, in my mind, a minimal positive effect, but
19 it's a well-controlled trial.
20 DR. NERENSTONE: Can we have a vote then?
21 How many people think that it was a well-controlled
22 trial?
23 DR. TEMPLE: Can I just comment first
24 before you vote?
25 DR. NERENSTONE: Yes. Dr. Temple?

1 DR. TEMPLE: We have regulations about
2 what an adequate and well-controlled study is, and
3 what exactly adequate means versus well-controlled
4 is not quite clear from those. But one of the
5 features of an adequate and well-controlled study
6 is that bias is minimized on the part of the people
7 who run the study and they people who analyze the
8 study and all those things. So some of these
9 discussions about when the endpoints you've chosen
10 need to be factored into your conclusion.
11 It could be properly designed and
12 randomized, but if you didn't believe the analysis
13 was carefully specified in something then you
14 wouldn't want to tell us that you thought it was.
15 So there's a lot of judgment to be made, but I just
16 want to say that that should be part of it.
17 DR. NERENSTONE: I guess that's why I
18 divided it into two. I think well-controlled most
19 of us think -- are in agreement that it was;
20 placebo-controlled was a good design that we
21 thought could minimize bias. Further discussion?
22 Larry?
23 MR. RUBENSTEIN: Are any of the clinicians
24 still concerned that we didn't have a proper
25 control of toxicity because both arms had the

1 wafer, or is there a feeling that that's really not
2 a serious problem?
3 DR. BUCKNER: I think that the bulk of the
4 data suggests that the toxicity of the Gliadel is
5 relatively low regardless of the comparator. That
6 a 6 percent risk of CFS leak is not high, and five
7 intracranial hemorrhages is not out of the range of
8 what one might expect to see in a normal
9 postoperative situation. And from the previous
10 approval, which basically was a slightly different
11 population but the procedure was the same, I think
12 the safety has not been a major issue for this
13 drug. Welcome the opinion of others.
14 DR. FINE: I agree 100 percent.
15 DR. NERENSTONE: Dr. Rubenstein?
16 MR. RUBENSTEIN: I had one more technical
17 question. The new indication that's asked for
18 extends for recurrent to all of malignant glioma.
19 Do we have any new evidence for recurrent that
20 would cause us to extend the indication from what
21 it was in the past ODAC and FDA decision?
22 DR. NERENSTONE: Dr. Martin?
23 DR. MARTIN: Do we have the additional
24 data? No.
25 DR. CARPENTER: I understand that it's

1 just simply because at the time was made with
2 recurrence you have the advantage of knowing
3 histopathology. At the time the decision is to
4 made here you won't have known histopathology. If
5 that's wrong, I stand to be corrected.
6 DR. NERENSTONE: To go back to the
7 question, do we think this was a well-controlled
8 trial? If it's unanimous we don't have to go
9 around the table. All those who think it was well-
10 controlled?
11 Any nays?
12 Thirteen yes.
13 Do we think it was an adequate trial? I'm
14 going to go around the room on this one. Any other
15 discussion? Do you want to go to the vote? We'll
16 go to the vote. Dr. Rubenstein, do you want to
17 start?
18 MR. RUBENSTEIN: Yes, I do.
19 DR. MOYE: I confess I have some
20 difficulty with the adequacy of this trial,
21 primarily because of the concerns for the analysis.
22 I just want to be clear, this is no reflection on
23 Dr. Piantadosi. He did a fine, expert analysis.
24 The only difficulty is that his phone rang too
25 late. Rather than get him in at the inception of

1 the trial, he's come in toward the end of the
2 trial, and he's done a fine analysis which was
3 hampered by, I'm afraid from my point of view
4 lethally hampered by the fact that his analysis
5 truly was not the prospectively stated analysis.
6 A prospective analysis from my point of
7 view is an analysis that's laid out before the data
8 are collected, so that you can design the trial to
9 collect the data that will provide the best
10 interpretation and the best estimates of effect
11 sizes and so on. That we don't see here.
12 Another nagging concern I have is that
13 many times when trials are corrupted by this kind
14 of problem the results are not reproducible. I'll
15 give you three different examples. One is --
16 unfortunately they're not in oncology. One is
17 visneranome, another is losartin, and third is
18 emlodapin. These trials, all three drugs were
19 initially studied with trials where the analysis
20 was perturbed, for understandable or not so
21 understandable reasons. Then when the trials were
22 repeated the results were very different.
23 Sometimes they were actually reversed.
24 So that is also part of my concern about
25 calling this trial adequate. So I must say I

1 believe it's not.

2 DR. NERENSTONE: So that's a no?

3 DR. MOYE: Yes, that's a no.

4 DR. NERENSTONE: Dr. Fine?

5 DR. FINE: Not being a statistician it's

6 hard for me to comment on that particular aspect of

7 it. I haven't chimed in on the issue of

8 histopathology, but needless to say, all of us in

9 this field know, and I've written extensively as we

10 all have, using the saying that the histopathology

11 is a greater predictor of patient outcome than any

12 therapy we currently have for this disease. So

13 it's not a trivial issue if even five or six

14 patients in a total patient population of 200 are

15 swayed in one direction versus another. Then

16 you're dealing with 0.05 and this kind of marginal

17 type of effect. That's a major, major factor.

18 So if you count that, that we don't have

19 the final analysis based on re-review, central

20 review of histopathology, that's my problem with

21 saying that this is a -- the analysis is fine. So

22 based on that I'd have to say the analysis is not

23 fine.

24 DR. NERENSTONE: So another no.

25 MR. GEORGE: I guess I'm going to have

1 another discussion before I vote. Can I have an
2 opinion from the FDA, the definition of adequate
3 again? What was -- I mean, if I think -- the
4 opposite of adequate is inadequate, I suppose.
5 DR. TEMPLE: We're just listening. The
6 phrase, adequate and well-controlled study is sort
7 of a buzzword. It means all of the above. It
8 means you randomize so that people are similar at
9 baseline, it means you maintain low -- you
10 eliminated bias by blinding and by specifying the
11 analysis. But that's okay. You can call them
12 adequate or well-controlled. We don't care. We're
13 just going to listen to what your reservations or
14 non-reservations are.
15 MR. GEORGE: All right. No.
16 DR. BUCKNER: No.
17 DR. SLEDGE: My remaining neurons are
18 voting 51/49, so yes.
19 DR. NERENSTONE: No.
20 DR. TAYLOR: No.
21 DR. KELSEN: Yes.
22 DR. BRAWLEY: Yes, just barely.
23 MR. LUSTIG: Perhaps using the definition
24 of -- it could have been more adequate, let's put
25 it that way. So I'm going to say no.

1 DR. CARPENTER: I think I'm going to vote
2 barely adequate, so yes.
3 DR. BLAYNEY: Yes.
4 DR. NERENSTONE: Six yes, seven no.
5 Two, Gliadel was considered to have a
6 treatment effect only in patients with recurrent
7 GBM and not in the overall population with
8 recurrent malignant gliomas. If this were a true
9 treatment effect, would this pattern be expected to
10 be present in newly diagnosed patients? I'm not
11 sure I understand the question. Could we have some
12 clarification from FDA?
13 DR. TEMPLE: Let me try. In the first
14 study, all of the action was in the glioblastoma.
15 In this, the ITT analysis is the more persuasive.
16 So what's going on? Now you heard a possible
17 explanation of that, the anaplastic tumors were
18 badly allocated -- inadvertently, but badly
19 allocated, which may explain the fact that the
20 glioblastoma didn't look better in this case. But
21 that's what that's about, isn't it sort of odd that
22 the whole picture reverses when you study the
23 initial treatment as opposed to when you study
24 recurrent? Aren't you surprised by that?
25 Obviously, you have to speculate here. We know you

1 don't know the answer for sure.

2 DR. NERENSTONE: Dr. Taylor?

3 DR. TAYLOR: But can we even think about

4 the answer when we don't know what the true

5 pathology was?

6 DR. NERENSTONE: I guess my question is,

7 do we even have to discuss this because we've

8 already voted no seven to six, and you've heard the

9 enthusiasm of the yeses?

10 DR. TEMPLE: That's fair enough.

11 DR. NERENSTONE: Number three, do the data

12 from number T-301 provide substantial evidence of a

13 survival benefit of Gliadel in patients with newly

14 diagnosed malignant glioma?

15 DR. TEMPLE: You don't have to answer

16 that. It wasn't a well-controlled study. It can't

17 provide evidence that we could accept, if that's

18 what -- so your vote can't be better than your

19 initial vote.

20 DR. NERENSTONE: So we're going to skip --

21 DR. TEMPLE: Wait a minute. Rick wants a

22 vote anyway.

23 DR. NERENSTONE: So is there substantial -

24 -

25 DR. PAZDUR: The emphasis is on

1 substantial because that's what's written in the
2 regulation.
3 DR. NERENSTONE: -- substantial evidence
4 of a survival benefit in Gliadel? Comments, or you
5 want to vote?
6 DR. TEMPLE: Substantial evidence in the
7 terms of the law means evidence from adequate and
8 well-controlled studies. That's the term of art
9 that the law requires.
10 DR. NERENSTONE: Larry, do you want to
11 start? Dr. Rubenstein?
12 MR. LUSTIG: Wait.
13 DR. NERENSTONE: You want some discussion
14 first?
15 DR. NERENSTONE: That's fine. Mr. Lustig?
16 MR. LUSTIG: If the implication of my
17 saying no to the question about whether this was
18 adequate is that therefore it has to be deemed as
19 not providing substantial evidence, then perhaps I
20 don't -- then if that's specifically how we're
21 connecting those two points, I want to understand
22 that, I guess.
23 DR. NERENSTONE: I think you're right. I
24 think the FDA would actually like us to separate
25 those two points, because they can be separated.

1 DR. TEMPLE: Which two?

2 DR. NERENSTONE: Number one and number

3 three. We are going to take this as separate

4 questions.

5 DR. TEMPLE: Let's just be clear. This

6 isn't advocating any position. The law says that a

7 sponsor has to provide substantial evidence of

8 effectiveness. It says, for purposes of this law,

9 substantial evidence means evidence derived from

10 adequate and well-controlled studies. At various

11 points it says, the only basis for approval is

12 adequate and well-controlled studies. So whether

13 this is an adequate and well-controlled study is

14 obviously debatable because you just split more or

15 less 50/50. But that is the only basis on which we

16 could say yes to approving a drug. But there's

17 judgment in whether something is adequate and well-

18 controlled.

19 DR. NERENSTONE: Let's take a vote on this

20 one separate, for the record here. Is there

21 substantial evidence of a survival benefit of

22 Gliadel in patients with newly diagnosed glioma.

23 Dr. Rubenstein?

24 MR. RUBENSTEIN: I think there's

25 substantial evidence but of a very modest survival

1 benefit. And I don't see evidence of a quality of
2 life benefit beyond just survival.
3 DR. NERENSTONE: Is that a yes or a no?
4 MR. RUBENSTEIN: It's a yes.
5 DR. MOYE: No.
6 DR. FINE: I actually need to comment on
7 this relative to what Craig was saying, and
8 relative to what, Robert, you were talking about.
9 So I voted no on the analysis based on the
10 histopathology. But we all want the same thing
11 here. First and foremost we want better drugs for
12 this terrible disease, but we want really better
13 drugs.
14 My no to the question, is this a good
15 analysis, again relates to the histopathology.
16 These are imminently answerable questions. The
17 data is there, and I'd hate that you have a
18 definitive no vote on my part when the data can be
19 looked at over the next month. And it may turn out
20 when you do the appropriate analysis it turns out
21 that the data holds up that Gliadel is positive.
22 So I actually, even though I voted no relative to
23 the analysis, I think the data, if it holds up as
24 it currently is, I would call that a substantial
25 benefit.

1 So I think that's an important --

2 DR. TEMPLE: But that would be because you

3 would then, upon seeing that data, consider it an

4 adequate and well-controlled study.

5 DR. FINE: Exactly. And since the data --

6 it's not like I'm -- it's not a kind of study

7 design problem where you'd have to go back and do a

8 whole new study. The data is there. It's just

9 that it hasn't been looked at or presented today in

10 a way that we can make that final judgment.

11 DR. TEMPLE: It sounds like you're saying

12 no, until and unless somebody satisfies your

13 concerns about the histopathology, in which case

14 your answer might be yes.

15 DR. FINE: I'm saying that if you take the

16 data at its face value I'd say that is a

17 substantial survival advantage and I would vote

18 yes, but there's a question about whether that

19 confounding variable is there.

20 DR. TEMPLE: It's important to distinguish

21 between a substantial benefit; that is, a

22 meaningful benefit, and whether there's evidence

23 that there's any effect at all. The questions here

24 being posed are, is this a study that can tell you

25 anything?

1 DR. FINE: And my answer is yes --

2 DR. TEMPLE: Maybe, if they do what you

3 want.

4 DR. FINE: -- if we look at that last

5 variable.

6 DR. BRAWLEY: Can I ask Dr. Temple a quick

7 question? Does the law allow us to take into

8 account that this is perhaps the best that we're

9 actually ever going to be able to get for this

10 particular disease?

11 DR. TEMPLE: Not in a direct way. The law

12 doesn't make a distinction between diseases that

13 are common, easy to study, hard to study. But as

14 is obvious from the debate here, whether a study is

15 a adequate and well-controlled study is something

16 that people can have different judgments on. We

17 all know what the issues are, and all of you do,

18 and yet half of you thought the answer was no and

19 half of you thought the answer was yes. So there

20 is enough judgment so that people can, in one

21 interior way or another, take those things into

22 account. But the law does not say you get

23 something for a good try.

24 DR. FINE: But lest there be any question

25 amongst the non-brain tumor experts on the

1 committee that I agree 100 percent with what Dr.
2 Friedman said, that if we got truly a two-month
3 survival advantage with any type of therapy in this
4 disease we'd all take it. That's good.
5 DR. TEMPLE: We certainly have no
6 reservations about that. We don't usually conclude
7 that a documented survival advantage isn't big
8 enough to be meritorious unless the toxicity is --
9 DR. FINE: I don't know if that was the
10 nature of the question but I want to just, as a
11 neuro-oncologist, make that clear.
12 DR. NERENSTONE: Dr. George?
13 MR. GEORGE: We're struggling with
14 adjectives in the law again, which causes me
15 trouble, because if you just asked me I would say
16 there is modest evidence of a modest difference.
17 But if you have to say -- how do I vote on
18 substantial is what you're really saying, right? I
19 mean, substantial is the big, key word here. So I
20 have to say no.
21 DR. BUCKNER: Editorial again. My
22 question is, in which newly diagnosed malignant
23 glioma is there benefit? There's no benefit in the
24 glioblastoma subset, which is the largest by other
25 the sponsor's analysis or by the FDA's analysis.

1 Since the majority of patients in this trial were
2 glioblastoma and since there was not supportive
3 evidence in glioblastoma I'll have to say no.
4 DR. SLEDGE: Yes.
5 DR. NERENSTONE: No.
6 DR. TAYLOR: No.
7 DR. KELSEN: Yes.
8 DR. BRAWLEY: Yes.
9 MR. LUSTIG: Yes.
10 DR. CARPENTER: Yes.
11 DR. BLAYNEY: Yes.
12 DR. NERENSTONE: Eight yes, five no. If
13 the answer to number three is yes, do trials CL-
14 0190 and/or 8802 together with T-301 provide
15 convincing evidence of a survival benefit in
16 patients with newly diagnosed malignant glioma?
17 This is a yes or no answer. Actually, just to
18 drive Dr. Somers crazy, why don't we start with Dr.
19 Blayney?
20 DR. BLAYNEY: Yes.
21 DR. CARPENTER: Yes.
22 MR. LUSTIG: Yes.
23 DR. BRAWLEY: Yes.
24 DR. KELSEN: Yes.
25 DR. TAYLOR: So we're assuming that it is

1 yes, that the first is adequate? I guess we have
2 to say yes.
3 DR. NERENSTONE: No.
4 DR. SLEDGE: Yes.
5 DR. BUCKNER: No.
6 MR. GEORGE: Surprisingly, yes.
7 DR. FINE: Yes.
8 DR. MOYE: No.
9 MR. RUBENSTEIN: Yes.
10 DR. NERENSTONE: Ten yes, three no.
11 Number five, is the toxicity profile of Gliadel
12 acceptable for patients with newly diagnosed
13 malignant glioma? Dr. Blayney, I'll start with you
14 again.
15 DR. BLAYNEY: Yes.
16 DR. CARPENTER: Yes.
17 MR. LUSTIG: Yes, but I feel the need to
18 make an editorial comment here. In the discussion
19 -- you know, we're all removed from this and we're
20 looking at these statistics and the numbers. I
21 have to say that -- I just have to reinforce the
22 point that when I look at these numbers and reflect
23 on my experience and look at the adverse events, we
24 shouldn't be flip about them. We shouldn't take
25 the numbers that are in here and feel good about

1 them. They're not good. But at the same time, I
2 understand right now it's the best we can get.
3 DR. BRAWLEY: Yes.
4 DR. KELSEN: Yes.
5 DR. TAYLOR: Yes.
6 DR. NERENSTONE: I'm just going to
7 editorialize because I don't think Gliadel is
8 really acceptable as this treatment because I'm not
9 convinced. Then I think that we don't know about
10 the toxicity to benefit ratio, so I have to say no.
11 DR. SLEDGE: Yes.
12 DR. BUCKNER: Yes.
13 MR. GEORGE: Yes.
14 DR. FINE: Yes.
15 DR. MOYE: No.
16 MR. RUBENSTEIN: I have to abstain because
17 I really don't think I can judge this issue as a
18 statistician.
19 DR. TEMPLE: Stacy, I think we're taking
20 the yes votes there to mean, if you thought it
21 worked would the toxicity be acceptable. I take
22 your two noes avoiding that issue. But it seems to
23 me that's what we were --
24 DR. NERENSTONE: Okay, then I could change
25 it to a yes. If we thought it was acceptable, yes,

1 is the toxicity acceptable, with reinterpretation.
2 DR. TEMPLE: But if our understanding is
3 not what everybody is saying, you should tell us.
4 But that's what we wanted to elicit there, is the
5 toxicity itself unacceptable.
6 DR. NERENSTONE: Dr. Buckner, did you want
7 to reevaluate in the light of their interpretation?
8 DR. BUCKNER: I said yes.
9 DR. NERENSTONE: You said yes. Someone
10 else said no. Dr. Moye?
11 DR. MOYE: Let's keep it that way.
12 DR. NERENSTONE: Eleven yes, one no, and
13 one abstention.
14 And the last, does the committee believe
15 that Gliadel provides clinical benefit with an
16 acceptable safety profile in patients with newly
17 diagnosed malignant glioma? Does this mean, would
18 we vote for approval? Cutting to the chase here.
19 DR. TEMPLE: In retrospect, I think our
20 questions allow a certain fuzziness in all this.
21 The logic of the whole thing is, if you don't think
22 it's a well-controlled study, probably all the
23 other things don't apply. But obviously what we're
24 seeing is a sort of gut reaction that there might
25 be something there, even though the studies leave

1 something to be desired. So you make your comments
2 and make your votes and we'll cogitate about what
3 you're telling us in the various votes.
4 DR. NERENSTONE: Dr. Blayney?
5 DR. BLAYNEY: Yes.
6 DR. CARPENTER: Yes.
7 MR. LUSTIG: Yes.
8 DR. BRAWLEY: Yes.
9 DR. KELSEN: Yes.
10 DR. TAYLOR: No.
11 DR. NERENSTONE: No.
12 DR. SLEDGE: Yes.
13 DR. BUCKNER: No.
14 MR. GEORGE: No.
15 DR. FINE: Yes.
16 DR. MOYE: No.
17 MR. RUBENSTEIN: Yes.
18 DR. NERENSTONE: Eight yes, five no.
19 Okay, there being no other questions, I'd
20 like to thank everybody. Our next meeting is
21 January 31st. It's going to be a one-day, one-
22 topic meeting. Thank you.
23 [Whereupon, at 5:13 p.m., the meeting was
24 adjourned.]

CERTIFICATE

I, **PAMELA BRIGGLE,** the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.

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