

1 DR. KAWAS: I am not sure I completely understand
2 how we could get around this issue but I have a low level
3 also of concern.

4 DR. GILMAN: Dr. Penn?

5 DR. PENN: I think the solution is simple, and
6 that is that the FDA should ask for the data from the
7 studies that have been presented to us, should review it and
8 make nimodipine available for all grades of patients with
9 subarachnoid hemorrhage if they think that is appropriate,
10 and then we would be done with the issue. It seems terrible
11 to be out of sync because a company has not gone back to ask
12 for this permission. I think something could be worked out
13 reasonably smoothly with the data that is now available.

14 DR. GILMAN: But you would have to have a control
15 group without and a group with and you would need placebo
16 control to do a rigorous study of the effect of nimodipine
17 in grade IV/V compared to grades I through III cases.

18 DR. PENN: I think the weight of evidence on that
19 issue is in now, and I don't think that it is deleterious in
20 those groups and I think there is no way that you are going
21 to get more information on that than we now have, and the
22 experts in the field feel strongly that it should be used
23 and we are out of step just because of a technical thing
24 that happened when there wasn't as much information
25 available.

1 DR. TEMPLE: Even if we can't find strong evidence
2 supporting effectiveness in grade IV and V it may be that
3 the evidence supporting detrimental effects is much weaker.
4 Currently the labeling really makes a point of that and I
5 think we need to look at it to see whether that is
6 reasonable or not.

7 DR. GILMAN: Well, it might be advisable to go
8 back and review the primary studies again because we have
9 heard about one study. Dr. Wiers, who I think had to leave,
10 had pretty contradictory information about that. Grade III
11 was the grade most at risk. That was puzzling.

12 DR. TEMPLE: That is what I meant by taking a
13 look.

14 DR. GILMAN: We are still trying to come to grips
15 with the question that Dr. Katz has posed for us so let's
16 move on. Dr. Lacey?

17 DR. LACEY: I have some concern about nimodipine
18 and its administration but in view of the contradictory
19 information that was presented, I am encouraged that perhaps
20 there is no need for real concern. So, I would hope that
21 there would be a review of the literature and if it supports
22 the use of it, then there is all reason to go with that. But
23 if it does not support it, then for me there is still a
24 quandary.

25 DR. GILMAN: Dr. Van Belle?

1 DR. VAN BELLE: No opinion.

2 DR. GILMAN: Dr. Grotta?

3 DR. GROTTA: I think that you compare your drug to
4 standard of care, and I think standard if care is the use of
5 nimodipine then it has to be included. I agree with
6 reviewing the criteria. In fact, I would expect
7 theoretically and pharmacologically that the two drugs, if
8 they are both neuroprotective, would act in a complementary
9 fashion and not contradictory.

10 DR. GILMAN: Dr. Brooke?

11 DR. BROOKE: I would second that. Nimodipine is
12 best medical practice. You can't really avoid its use, and
13 there is not enough in this data that we have been presented
14 with to make me think that nimodipine was clearly having a
15 deleterious effect in combination. So, I don't think that I
16 would have any problem with using nimodipine.

17 DR. GILMAN: Dr. Brooke has to leave us shortly
18 but he has given me a statement related to the two final
19 questions that we will get to.

20 Question four concerns the effects, if any, of
21 baseline differences between treatment groups. Are there
22 concerns about the baseline differences between treatment
23 groups?

24 Well, I have significant concerns about the
25 differences between the treatment groups in the trials that

1 we have examined. To go back again, the initial two studies,
2 as I reviewed them retrospectively, left me a bit puzzled as
3 to why the FDA did not recommend a large men and women study
4 rather than women alone. I have heard the answer. Obviously
5 hindsight is 20/20. I think it would have been better
6 perhaps to have a large group of both men and women all
7 grades examined with drug and with placebo, double-blinded.
8 So, I do have concern about the baseline differences between
9 treatment groups in the studies that we have reviewed here
10 today. There are gender differences. There are drug dose
11 differences, age differences, etc. So, yes, there are
12 concerns.

13 Let me go the other way. Dr. Grotta?

14 DR. GROTTA: Again, I think the whole data set
15 should be looked at for the predictors of outcome, and I
16 think that those need to be within the study -- if you do
17 another study you just need to ensure a balance between the
18 different groups on those variables.

19 DR. GILMAN: Dr. Van Belle?

20 DR. VAN BELLE: Yes, I think the issue is that the
21 way the endpoints were defined retrospectively were bound to
22 give a fairly high chance of having groups that differed at
23 baseline, and no amount of adjustment will take care of that
24 problem. We will always be left with the question what does
25 it really mean.

1 DR. GILMAN: Dr. Lacey?

2 DR. LACEY: Yes, I feel that there are differences
3 that should be of concern to us, but I think enough has come
4 up in the various discussions that for future study things
5 can be identified reasonably.

6 DR. GILMAN: Dr. Penn?

7 DR. PENN: I don't have anything to add.

8 DR. GILMAN: Dr. Kawas?

9 DR. KAWAS: Just to say there are always baseline
10 differences between groups, otherwise the FDA and the
11 sponsor wouldn't have something to massage to make the
12 result look more in their direction. None of the baseline
13 differences that are in any of the studies, however, that we
14 reviewed really concerned me and I don't think they were
15 responsible for the outcomes of the studies in any of these
16 cases in a convincing way. So, in the sense of the effects
17 of the baseline differences between groups I actually have
18 pretty much no concern.

19 DR. GILMAN: Dr. Drachman?

20 DR. DRACHMAN: Well, if there really were no
21 differences the very dramatic result in 32 and not 29 would
22 be very puzzling. I have sort of looked at that and worried
23 about it over and over again. I still don't quite know why
24 men did so dramatically better in the one than the other.
25 So, I think there must be baseline differences or we have

1 tossed an unfair coin one way or another and got a very
2 strange result. Nevertheless, the retrospective grouping is
3 always a way of finding imbalances, and the effort to
4 redress that leaves one open to the failure of the notion of
5 randomization. So, in the future randomize; say what you are
6 doing. But I am still very puzzled by 32 versus 29.

7 DR. KAWAS: Can I just comment? I think that one
8 of the main issues with regard to baseline differences might
9 flow into the mandate that Dr. Temple gave us, which is
10 should any of these differences be stratified in future
11 studies.

12 DR. GILMAN: Of course, that is the concern with
13 retrospective studies. The cases were not gathered with
14 stratification in mind to test particular questions in
15 particular subgroups. So, one can get into all kinds of
16 trouble with retrospective analyses and I think that is just
17 what we are seeing here.

18 But would you still maintain though that you are
19 not concerned about baseline differences, Dr. Kawas?

20 DR. KAWAS: Yes, I guess I would only because all
21 the ones that we have seen -- I am not convinced. They are
22 just as convincing as the other things. I mean, the first
23 study would say that the baseline difference that was
24 irrelevant was sex. Being a man was the important thing.
25 And, I realize we have limited evidence to look at even

1 gender because two out of the three remaining studies don't
2 even give us an opportunity to look again at men. The data
3 doesn't coalesce in any way that makes me think that there
4 is a particular baseline difference that is very important
5 for creating these results right now. That is not to say
6 there isn't one; I just can't identify it.

7 DR. GILMAN: All right, thanks. Let's then go to
8 question six, and that has to do with the sponsor's
9 integrated analyses.

10 I feel very strongly about this issue. I guess it
11 was pretty obvious earlier that I don't see the rationale
12 for and, in fact, I take strong exception with the
13 integrated analyses that we have seen. The sponsor has mixed
14 together different studies with different genders, different
15 drug doses, and had us look at a bar graph that was just
16 totally misleading. In addition, we want to show that a
17 particular effect can be replicated. It is not always
18 necessary now with the change in the law. It is possible to
19 prove a particular drug with a single trial provided a
20 series of guidelines are followed. I am not going to review
21 them at this point.

22 But I would certainly like to see replication, and
23 the frustrating aspect of these data has been that one study
24 shows a significant effect but the next study doesn't
25 replicate that effect and we have just gone on with four

1 studies now, almost getting nowhere. We see something
2 interesting and then it vanishes, until finally we have a
3 prospective study that shows something. It does show
4 something that appears to be significant for women but then
5 I have very little confidence that replication of that will
6 show it again unless it is done correctly, done well. So, I
7 don't think that integrating the various studies, putting
8 them together, gets us anywhere. It just confuses the
9 matter. Dr. Grotta?

10 DR. GROTTA: Well, I also feel strongly about this
11 because I think that actually we have missed an opportunity
12 here. I agree with what Dr. Gilman said. I think that I
13 don't like the integrated analysis, and I am not a
14 biostatistician but I think, had the data been presented
15 differently we, as a group, might have reached a different
16 conclusion.

17 So, let me take a minute to explain why I think
18 that. Three out of these four studies showed a very strong
19 trend, if not a significant effect, on the outcome of
20 mortality. Study 32 -- and you correct me if I have got the
21 figures wrong, but for all males, which is the subgroup of
22 interest in study 32, for all grades the mortality rate was
23 25.3 versus 2.1. In study 29 for all males the mortality
24 rate was 12.7 versus 8.6, again, both of those in favor of
25 tirilazad. In study 63 for all women the mortality rate was

1 15.1 versus 12.9, again in favor of tirilazad. In study 65,
2 which is the other large study and all women, and even
3 there, there was a little trend, 18.8 versus 18.0. So, in
4 all four studies the mortality rate was less, and in one of
5 them it was highly significant and in two of the others
6 there was a strong trend.

7 Had you done a meta-analysis on mortality in the
8 populations of interest, I think that that would have
9 probably turned out to have a positive meta-analysis for
10 mortality. That is the way a lot of the anti-platelet drugs
11 for stroke prevention got approved. A lot of the studies
12 were underpowered to detect a significant effect but they
13 showed a trend, and in a series of studies all going the
14 right way I think I could have been convinced.

15 DR. GILMAN: Dr. Van Belle?

16 DR. VAN BELLE: Well, let me respond to that. A
17 meta-analysis assumes that you have independence of studies
18 in some sense, and I think you would be hard-pressed to
19 argue that these studies, the way they were set up, were in
20 fact independent. That is point number one.

21 The other point is that most analyses are
22 integrated analyses in some form or another. When you
23 randomize subjects to treatment one and treatment two you
24 can always get subgroups out and say, you know, that things
25 were integrated over that. So, to my mind, the important

1 thing is are you integrating homogeneous groups or
2 heterogeneous groups? In this case it was clear that there
3 were heterogeneous groups, and that is where my concern
4 would come about. That is all.

5 DR. GILMAN: Thank you. Dr. Temple?

6 DR. TEMPLE: Can we inquire, would you explain
7 what you mean by not being independent? They were separate
8 studies? Why were they not independent?

9 DR. VAN BELLE: They were not independent in the
10 sense that when we go to categories IV and V they were
11 defined by looking at the previous studies. So, that
12 introduces a kind of dependence into the four studies.

13 DR. TEMPLE: I think the suggestion was that they
14 should have simply done a meta-analysis of the four studies
15 as originally randomized.

16 DR. VAN BELLE: I am sorry, I didn't get that
17 point.

18 DR. TEMPLE: I think that would not come out --

19 DR. GROTTA: Those figures that I mentioned were
20 for all grade patients in the first two studies, just
21 limiting it to men, and the second two studies, of course,
22 were just women. But all women, all grades for the second
23 two studies and all men, all grades for the first two
24 studies, and they were independent studies. So, I don't see
25 why you wouldn't be able to meta-analyze them.

1 DR. VAN BELLE: Your point is well taken. I was
2 thinking that you were talking about the studies as we were
3 presented with today. There still is the second aspect
4 though of doing a meta-analysis of studies that are not
5 homogeneous.

6 DR. LACEY: I think the sponsor's integrated
7 analysis as presented today -- it seemed to be intended to
8 be convincing and I looked at it in that way, that someone
9 was trying to convince me of something. I looked at it more
10 as a cumulative percentage, as you would look at that. I had
11 seen the data separately and, therefore, I feel that I was
12 able to make a judgment regardless of that having been
13 presented. So, I would hope in the future that they would
14 use a more appropriate analysis, whether that is
15 meta-analysis or what, but a more appropriate analysis than
16 the one given today but I didn't find it terribly
17 distracting.

18 DR. GILMAN: Dr. Katz?

19 DR. KATZ: Yes, maybe to make this more explicit,
20 Dr. Grotta, you are suggesting -- well, let me ask this as a
21 question, are you suggesting that if they performed the sort
22 of meta-analysis that you described and it turns out
23 significant that you would not require additional studies to
24 look at some replicated finding? Would that be enough to
25 provide substantial evidence in your mind?

1 DR. GROTTA: Yes, in my mind because, as has been
2 said multiple times here, all these trials have trended in
3 the right direction. One of them was highly significant, one
4 of them was borderline and two of them weren't. So, I mean,
5 it depends on whether you believe in approving a drug on the
6 basis of a meta-analysis or whether you require two
7 independent studies. I suppose that is a matter of how many
8 studies go into the meta-analysis, the quality of them and
9 the clinical situation. I guess that in this situation,
10 where -- of course, more studies would always make me feel
11 more comfortable, and I tried to convey earlier that I have
12 a nagging feeling that there is a biological signal here
13 that there is some activity and I just don't think that we
14 are picking up on it right. I am bothered by the possibility
15 of type-2 error but if a proper meta-analysis of these four
16 studies, four randomized studies that have been carried out
17 in a prospective, controlled fashion came up positive I
18 think I would be convinced.

19 DR. TEMPLE: Before we leave that, remember the
20 numbers. Study 32 was positive overall. Study 29 is a wash
21 overall. So, it is not going to add to anything.

22 DR. GROTTA: Correct me if I am wrong, but I think
23 in study 29 the mortality in males, all males, was 12.7
24 versus 8.6.

25 DR. TEMPLE: So, you are not talking about a

1 meta-analysis of all data, just in males?

2 DR. GROTTA: Well, I think if the basic premise is
3 that the dose was wrong -- and I am willing to give that
4 part of it away but, again, I am on thin ground, but it
5 seems to me illogical -- and reasonably appropriate to
6 separate by gender for this particular problem given the
7 different bioavailability of the drug in the two genders.

8 DR. KATZ: I am not a biostatistician either, but
9 we heard earlier that the integrated analysis which was
10 presented in terms of a histogram did exclude women in the
11 first two studies because that is what the company wanted.
12 In other words, they wanted 6 mg in men and 15 mg in women.
13 We all want things. The question is whether or not it is
14 appropriate to do that. To say that women exposed to 6 mg is
15 inappropriate to include because 15 mg is the correct dose,
16 that has yet to have been established I think in women. So,
17 again, it would be interesting to hear what the
18 statisticians in the room think, but the methodology is
19 complicated; it is not straightforward. At least to me, it
20 would seem that those women would need to be included at
21 least.

22 DR. GROTTA: The only thing about gender is that
23 it is hard to get it wrong. In trials, when you start
24 splitting data and studies, were they recognized right and
25 all the rest? At least as far as gender is concerned, it

1 should be a pretty easy thing to segregate.

2 DR. KATZ: Right, but as I understood it, the
3 reason that the women in 32 and 29 were excluded from this
4 so-called integrated analysis was because they weren't
5 studied at the right dose. It is not the dose that the
6 company is going for. We don't know what, if any, dose is
7 right in women, or men for that matter. All we know is what
8 was studied. As I say, if we had independent evidence I
9 suppose that 15 mg in women was the correct dose and 6 mg
10 was clearly incorrect perhaps a case could be made for
11 excluding them. But, nonetheless, you do in general want to
12 include all patients randomized in an analysis.

13 DR. GROTTA: But we heard yesterday that for
14 anti-platelet drugs, particularly aspirin, that the dose of
15 aspirin was approved, or changes in the dose of aspirin had
16 been made based on going back and looking at the burden of
17 evidence in trials, and sometimes the trials were done with
18 multiple doses and you take the 50 mg patients from this
19 study and the 30 mg patients from this other study and it
20 looks like there is an effect so we are going to approve a
21 lower dose. I think we have to be consistent here, and I
22 think that there are certain things in trials -- again, I am
23 talking now from logic more than I am from strict
24 biostatistical rules and I would have to defer to a
25 biostatistician, but I think it would be appropriate to get

1 their input at this point. But it seems to me that there are
2 certain things that can go into trials and you can use for
3 meta-analysis. Dose and gender seem to be two of some of
4 those things.

5 DR. TEMPLE: The problem with meta-analyses, just
6 as is the problem with individual studies, is that you
7 develop multiplicity when you have ten ways to do it. So, a
8 perfectly logical analysis to carry out is all four studies
9 as planned. One can object to the fact that one didn't have
10 men, though I am not sure I would make that objection. One
11 could do that. One could then look at only the men in one
12 and only the women in the other for the logical reason that
13 they got the wrong dose in the first two. Then one can do,
14 which is what they did, the grade IV/V people in all the
15 others. None of them are inherently absurd. They are all
16 perfectly sensible.

17 The thing is there is such a large choice that you
18 have to figure out what sort of correction you make. It is
19 really the same problem as with any other subgroup kind of
20 analysis. I think that is the problem. I am not as outraged
21 by the attempt to put the data together. I think what they
22 were trying to do is show you that if you look at this
23 plausible subset and you throw all the data together it has
24 a certain strength to it. Personally, I think it is never
25 all that much stronger than the individual components are

1 anyway, but that was the idea. I think everybody knows that
2 those kinds of analyses aren't the prospectively defined
3 analyses and have to be given a certain amount of skepticism
4 when you look at them, and you have treated them with
5 considerable skepticism.

6 DR. GILMAN: Dr. Cui?

7 DR. CUI: I just want to make comments about if we
8 really see a consistent result due to the nature of this
9 kind of assay, sort of the data dredging strategy, say, you
10 give me 4,000 patients; now you give me the freedom to
11 choose a subgroup and endpoint I can easily work out four
12 subgroups with similar patient populations and a certain
13 endpoint to give you all consistent results. So, you have to
14 bear that in mind in interpreting.

15 DR. GROTTA: And I agree, and that is why I don't
16 like the grade IV/V and all this because I do think it was
17 very retrospective and post hoc data dredging. But I do
18 believe that dose gender issue is sort of like treating a
19 patient that doesn't have the disease. There are certain
20 overriding things in a trial that define whether the
21 population is being treated. I don't believe the women in
22 studies 29 and 32 were being treated. Okay? It was basically
23 like they were being given placebo. So, I do think that when
24 performing this sort of analysis there are certain
25 overriding biological considerations that might allow you to

1 make a single assessment. I think in this case the women in
2 29 and 32, it is logical to exclude them from analysis
3 because of the fact that I think they were not exposed to
4 the drug basically.

5 DR. GILMAN: To continue then, I think we are up
6 to Dr. Penn.

7 DR. PENN: I dare not wade into meta-analyses. I
8 feel very uncomfortable with them.

9 DR. GILMAN: But without dealing with them, how
10 about your thought about integrated analyses, meta or
11 otherwise.

12 DR. PENN: Well, if I had an integrated analysis I
13 would rather have it be a meta one that I don't understand
14 than an integrated one that I do.

15 [Laughter]

16 DR. GILMAN: Dr. Kawas?

17 DR. KAWAS: I agree with Dr. Temple basically. I
18 am not as disturbed as some people are. When I first started
19 hearing the studies I wrote a note to myself how can we put
20 this data all together. But then I realized that the studies
21 were just too dissimilar to do that. I think we are fairly
22 agreed on this point and what effect it has on our
23 interpretation of the data.

24 DR. GILMAN: Dr. Drachman?

25 DR. DRACHMAN: The minute we talk of doing some

1 study in subarachnoid hemorrhage we are immediately
2 beginning to integrate many different processes. We have
3 sort of danced around this, but I think we really should
4 deal with it. My old mentor, E.P. Richardson said when an
5 aneurysm ruptures, that is rather like turning a fire hose
6 on a bowl of jello, which I think really describes it rather
7 well. Death or bad result in aneurysmal subarachnoid
8 hemorrhage may be due to the initial bleed, rebleed later
9 on, thrombosis, death of adjacent tissue, bad surgical
10 results, and on and on. Were this merely blood that appeared
11 in the subarachnoid space we would have only one thing to
12 deal with. What are we dealing with here? We are dealing
13 with so many heterogeneous mechanisms that the notion that
14 one miraculous drug will rescue many patients whether they
15 have herniated their brains and compressed their brain
16 stems, or whether they have jetted blood into their frontal
17 lobes, or whether in fact they have developed emboli from
18 the aneurysm that then led to an infarct in another part of
19 the brain seems highly implausible.

20 So, at the very least, no matter what we do, we
21 have integrated seven or eight different mechanisms to begin
22 with. Therefore, I do believe that the idea that you would
23 pick out a subgroup based only on severity, without even
24 exploring whether that is due to herniation or whether that
25 is due to dural hemorrhages and brain stem, and on and on,

1 becomes very unlikely. Since we are looking at a very, very
2 heterogeneous entity, therefore, we must I think integrate
3 data. The way Dr. Grotta recommended makes sense to me.
4 Picking out subgroups based on severity may be helpful in
5 one or another way but it does not say whether we are
6 dealing with infarction, damage due to hemorrhage,
7 herniation of whatever.

8 So, the short answer is that I do believe that
9 some sort of integration is needed, but that this problem is
10 a severely vexed one because we have lumped under a single
11 rubric something that is so heterogeneous in mechanism that
12 the notion that one drug would fix much of it seems highly
13 unlikely to me.

14 DR. GILMAN: Dr. Katz?

15 DR. KATZ: Just to be fair, many of the diseases
16 that treatments are offered for are heterogeneous and
17 complicated, and we have no hesitation in approving drugs
18 that do just a little bit maybe for just one part of it. So,
19 I don't want the impression to be left -- you may find the
20 findings sort of hard to put together in your mind but there
21 is certainly no requirement that there be a major effect on
22 all mechanisms of a disease process for a drug to get
23 approved.

24 DR. DRACHMAN: No, no, I never would think that
25 there must be a major effect but the notion that by slicing

1 this pie in a variety of different ways -- gender, the grade
2 -- we will tease out that group without also considering
3 what it is we are treating seems rather unlikely. So, I
4 think we started by integrating a disease, and when we then
5 subdivide that we are in more trouble. I think you have to
6 integrate the data, but it must be done fairly rather than
7 retrospectively.

8 Just a word on that, that is the entity I am sure
9 you are very familiar with which I refer to as the 6 ft.
10 left-handed women syndrome -- you give a drug and you look
11 through all the data and discover that only women over 6 ft.
12 who are left-handed seem to benefit. Well, you can always
13 find if you have enough entities. Here, I am not sure that
14 the various maneuvers that were done to subdivide make more
15 sense going forward. Going backwards, retrospectively you
16 can find anything.

17 DR. GILMAN: Dr. Temple?

18 DR. TEMPLE: Again, this sort of raises the
19 question of what to do next, and I know you want to get to
20 that later. Are you suggesting as a preliminary matter that
21 you are not persuaded that the most promising place to look
22 is in the more severe group? I mean, there was one attempt
23 to look at that group specifically that was prospective, and
24 there was in that study a clear difference in the kind of
25 benefit seen. The excluded group didn't really show

1 anything; it went the wrong way, and the prospectively
2 determined group looked good. Are you suggesting that lead
3 should be ignored for future studies?

4 DR. DRACHMAN: I would never want to ignore a
5 lead. The lead is good. But I really would worry that when
6 you look at the IVs and Vs you are still looking at a very
7 heterogeneous group. You may be looking at people with dural
8 hemorrhages and brain stem who have no chance of ever
9 getting better again and, likely, will either be vegetative
10 or dead, while you also may be looking at individuals who
11 are transiently severely anoxic.

12 DR. TEMPLE: Understood, but having said that,
13 what does that imply to you about where they should go?

14 DR. DRACHMAN: I don't know, but I agree that the
15 drug may have biologic properties, as was suggested by,
16 first of all, the sponsors, secondly, by Dr. Grotta
17 recently, a moment ago. How one would go forward really
18 would depend again on looking very closely. Herniation is
19 bad news. That is very different from anoxia or ischemia. I
20 have heard very little about that and how those data look. I
21 think going forward to make a major investment, yes. The IVs
22 and Vs look somewhat promising but why were they IV and V? I
23 know very little about that.

24 DR. GILMAN: Dr. Katz?

25 DR. KATZ: Let me just ask the other obvious

1 question. What is your view about whether or not a
2 meta-analysis done on the data that exist by protocol, in
3 other words, all patients, all neurogrades. Is that
4 something you would like to see? Is that something, if the
5 results were positive, you would find compelling? I am sort
6 of interested that the issue has been raised. I mean,
7 meta-analysis is a can of worms, but since it has been
8 raised I am just wondering what people think about whether
9 or not that is something that, if it was positive, would
10 carry the day for you now, without additional data.

11 DR. DRACHMAN: Not now, not carry the day, but it
12 surely would point out that one of the more important
13 mechanisms was included within this heterogeneous group. I
14 mean, sure, it may be that some large proportion have in
15 common enough so that by looking at all the data you would
16 be able to find it. You may even be able to slice it better.
17 But I rather doubt that a meta-analysis, given what we have
18 seen, would be significant. So, again, subjunctive; contrary
19 to fact.

20 DR. GILMAN: Dr. Grotta?

21 DR. GROTTA: But what if it were? Let's just give
22 a hypothetical that you have the amount of uncertainty --
23 let's say the studies maybe wouldn't be positive. Let's say
24 the studies were a little bit more positive than they are,
25 and a proper meta-analysis were done and it showed

1 statistical significance.

2 DR. DRACHMAN: That I would need to see. It would
3 be much more persuasive. We can, I am sure, be very certain
4 that it wouldn't or we would have seen that and not all the
5 other stuff. I mean, if frogs had wings they would fly but I
6 don't think that is the case here.

7 DR. GILMAN: Dr. Temple?

8 DR. TEMPLE: Well, you can already predict the
9 results of this. I don't know what happens if you throw all
10 the studies together, but we know there was only one study
11 that was overall positive for the entire population. So a
12 meta-analysis would be driven by that study if it remained
13 positive after dilution by the other three which I do not,
14 just intuitively, think it would. It doesn't really provide
15 you any more information than you had before. One of the
16 trouble with meta-analyses where you know all the components
17 going in is that you can predict the outcome or come very
18 close. It is only when somehow you take a bunch of small
19 studies that individually don't show anything and then at
20 the end you have a p that is as long as your arm, those can
21 be sometimes very convincing. But in this case it is not
22 easy to see how that would become persuasive.

23 DR. GROTTA: But aren't met-analyses affected by
24 the size of the study? So, the first two studies aren't
25 going to nearly lend the weight that the second two studies

1 would.

2 DR. TEMPLE: The first two studies are good sized.
3 It is just that the grade IV/V men are rather small but they
4 are pretty big on their own.

5 DR. GROTTA: The number of men, right, and the
6 number of women. The Ns in the second two studies were twice
7 what they would be in the first study because the second
8 studies were just women and the first studies were both men
9 and women.

10 DR. GILMAN: A lot of this discussion I think is
11 past the point. The point is do we have an effect, do we
12 have a beneficial effect of a drug on a serious illness that
13 convinces that the drug is better than placebo, first.
14 Second, if that is the case, can it be replicated
15 independently? This is the scientific method, that you have
16 a hypothesis, you test the hypothesis, you get an answer.
17 The answer could be due to chance or could be due to any of
18 a number of factors and so you want a separate method of
19 verifying it independently, presumably or hopefully using
20 the same techniques, the same cases and so on. I think we
21 beg the question when we get to looking back over four
22 studies that, from my perspective, had different baselines,
23 different genders, different drug doses, etc. So, I am not
24 persuaded that a meta-analysis would do anything more than
25 show us that one of these studies prospectively showed

1 something important, maybe important. Dr. Van Belle?

2 DR. VAN BELLE: I still want to go back to the
3 point that I made earlier about meta-analysis. Before you do
4 the meta-analysis, that is to say before you integrate, you
5 see whether what you are integrating is comparable or not,
6 and I think in this particular case that is not so. So, I
7 would doubt the usefulness of a meta-analysis.

8 DR. GILMAN: I think you have said that more
9 succinctly than I could. That is exactly what I was trying
10 to say.

11 Let me ask the agency, do you wish more of this or
12 shall we get to the two final questions? Can we proceed?

13 Well, we have been asked to answer two questions
14 that are posed for us, and they are the following: First,
15 has the sponsor submitted substantial evidence of
16 effectiveness for the proposed indication sought for the
17 treatment of aneurysmal subarachnoid hemorrhage to improve
18 survival and functional outcome in patients with poor
19 neurologic function following the initial hemorrhage?

20 Let me again start off by saying no, in my view
21 the sponsor has not submitted substantial evidence showing
22 that there is any beneficial effect. Let me follow that up
23 by answering Dr. Temple when he asked what sort of study
24 should be done to answer this question. We have studies that
25 initially suggested that perhaps all men would benefit from

1 this treatment. Then we had a study suggesting that perhaps
2 only grade IV/V men would benefit from this treatment. Then
3 we had a study, the one prospective study suggesting that
4 perhaps women at grade IV/V might be benefitted. Then we had
5 a question about whether grades I through III might be
6 damaged. Those are questions; there are no answers. I don't
7 think we know this yet. Then we have to throw in the problem
8 with respect to nimodipine.

9 So, my suggestion is that first you go back to the
10 literature, as Dr. Temple indicated they will do, the agency
11 will do, and look at what you have there with respect to
12 nimodipine effects in good studies, well-controlled studies
13 on these various different grades and see if you can verify
14 what appears to be common knowledge in the neurosurgical
15 community, that all grades seem to benefit from nimodipine.
16 I don't take that at face value. I would like to see data to
17 verify that issue.

18 If you do, if you find that in fact they are
19 correct, then I would suggest that maybe the sponsor would
20 want to go back and do another trial. And, my suggestion is
21 that this trial be a large one on both men and women, I
22 would hope with the same kinds of approaches with respect to
23 grading, and I would personally prefer that they use a
24 commonly used grading scale, whatever that scale may be. It
25 is probably not hard for the experts in the room to say,

1 well, a modified GOS is fine; we can do it in a couple of
2 minutes, but often this is the sort of treatment that would
3 be applied to people in critical situations with changing
4 status for patients rapidly over time and it is obviously
5 much better if you can have a simple, rapidly applied
6 grading scale to determine the grade of the patient. So, I
7 would like to see grades I through V evaluated in another
8 study, both men and women.

9 DR. KATZ: Let me just explore that a little.
10 Obviously, there is a fair amount of conflicting data here
11 but study 32 suggests that in men there is a chance that it
12 may work in everybody. Subsequent data suggests that if
13 there is anything in the women it is only in the high
14 neurogrades. The question is which of those findings -- in
15 other words, suppose they did a second trial only in IV/V
16 men, women, whoever, is that what you would like to see? I
17 know you want to include all neurogrades, the question is in
18 which group of patients has there been, if any, a sufficient
19 finding already that it is sort of ripe for replication?

20 DR. GILMAN: None. As I see it, there are
21 conflicting data irrespective of which grade you look at.
22 There are some suggestive data that grades I through III may
23 be damaged by the treatment. There are some data suggesting
24 that grades IV/V may be benefitted by the treatment.
25 However, none of this is clear from what we have. We have

1 one study in which there is a positive beneficial effect
2 prospectively, and that is grade IV/V women in the final
3 study done. I think they need to go back and do a proper
4 trial.

5 DR. TEMPLE: Let me press that point. Suppose,
6 because of efficiency and a desire to get there, the company
7 said, well, fine, the first thing we are going to do -- we
8 are going to do more later maybe but the first thing we are
9 going to do is replicate the finding in 63 because it was
10 prospective and that would then be a replicated finding in
11 women with high neurogrades. That wouldn't be the first time
12 someone had studied one part of an array of a disease. Would
13 you have a problem with that, or do you think it is less
14 optimal, where do you come out?

15 DR. GILMAN: I have a problem with it because some
16 years back when you had studies 29 and 32 your
17 recommendation was to go back and study just women, hoping
18 that you could replicate a finding in grade IV/V men. Now
19 here we are, some years later.

20 DR. KATZ: Briefly, we were hoping that they would
21 replicate a finding in all women, not just IV/V.

22 DR. GILMAN: I am sorry, you are right. That is
23 correct, in all women. But we wind up now, with the
24 committee having deliberated over this day and having read
25 thoroughly for a considerable period of time, and we are

1 saying no, the sponsor has not -- at least I am saying the
2 sponsor has not submitted substantial evidence of
3 effectiveness. I am concerned that there are so many
4 questions before us that if the sponsor goes back and tries
5 to replicate the findings on grade IV/V women, those
6 findings may not be replicated. We won't know, even if they
7 are replicated, whether the medication will help men grade
8 IV/V or men grade I through III or whether it will be
9 deleterious to men or women at grades I through III. We will
10 still have multiple questions even after that is done. That
11 is the concern.

12 DR. TEMPLE: I suppose one could do a study in,
13 say, both men and women with your primary hypothesis being
14 that there is a benefit in grade IV and V and studying other
15 people to see what happens.

16 DR. GILMAN: What other people?

17 DR. TEMPLE: The other grades.

18 DR. GILMAN: Other grades?

19 DR. TEMPLE: Yes. It makes a big difference in the
20 likelihood of success if the hypothesis is correct.

21 DR. GILMAN: Let me understand you. You are saying
22 study all grades of men and women?

23 DR. TEMPLE: Well, not really different from what
24 was done with study 63. That happened to be just women.

25 DR. GILMAN: It was just women.

1 DR. TEMPLE: The hypothesis testing component
2 would then be grade IV/V or whatever scale one decides to
3 use, and the exploratory component would be the other grades
4 where the data in support of benefit is much weaker.

5 DR. GILMAN: Well, I would have no problem -- in
6 fact, yes, I would suggest a study in which you look at men
7 and women, all grades. Your hypothesis can be focused on
8 grades IV/V. There is reasonable evidence suggesting that
9 may be correct. But I would look at grades I through III as
10 well to see whether, in fact, it is damaging. I rather doubt
11 that it will prove to be damaging but that remains to be
12 seen. So, yes, you can use the hypothesis that you
13 recommended.

14 All right, let me go back around the table. So,
15 the question then is, first, whether the sponsor submitted
16 substantial evidence of effectiveness. I will just start
17 with Dr. Drachman.

18 DR. DRACHMAN: No. I do not believe the evidence
19 was sufficient.

20 DR. GILMAN: Do you want to comment on Dr.
21 Temple's question about what should be done?

22 DR. DRACHMAN: I would agree with that, that it
23 should be a broader trial but, as you say, with men and
24 women at all grades, and with the primary hypothesis that IV
25 and V would benefit the most.

1 DR. GILMAN: What would you say about the use of
2 nimodipine?

3 DR. DRACHMAN: That would be very difficult not to
4 use. I believe that that should be used but, again, the
5 review of the literature would be of value.

6 DR. GILMAN: Dr. Kawas?

7 DR. KAWAS: I am not going to add very much. I
8 would be satisfied to see replication of almost any of the
9 findings, and the design suggestions I think are dependent
10 on what somebody wants to prove. If the indication that
11 people are interested in is for grade IV and V and they just
12 brought in IVs and Vs and did the study and had a positive
13 effect, then that is fine with me.

14 But I think the thing that is bothering everybody
15 in this group is that when we get conflicting results from
16 the different studies we all have the sense that there is
17 something going on here, that there is some benefit here and
18 we don't want grades I, II and III to be left out. We don't
19 want women to be left out. We don't want whatever, and I
20 think that is why everyone is pushing for more inclusive
21 studies which are really sort of a way of looking at all of
22 the questions once again.

23 DR. GILMAN: So, your response to whether the
24 sponsor submitted substantial evidence of effectiveness is
25 no?

1 DR. KAWAS: Right, correct.

2 DR. GILMAN: Thank you. Dr. Penn?

3 DR. PENN: The response is no, and I am afraid it
4 is a very difficult decision as to what to do next in terms
5 of study design, and if the company wants to go ahead with
6 anything more is going to have to make a guess. We are not
7 dealing with a major effect because we have such a messy
8 field in terms of trying to change the outcome with just one
9 measure or drug interposed. I think unless they guess right
10 they are probably not going to have a significant finding
11 unless they have a huge number of patients that probably is
12 not practical to run.

13 So, I think it is a major dilemma as to how to
14 design the next stage because if you take three hypotheses
15 up front and test them, you are going to need many more
16 patients than we have seen before to get significance. If
17 you choose one, you may once again choose the wrong one.

18 DR. GILMAN: Your comment on nimodipine? I think I
19 know what you are going to say but would you tell us?

20 DR. PENN: Oh, I hope the FDA straightens out
21 nimodipine. As a neurosurgeon, it would make me feel a
22 little bit better using it if it were on the label, but not
23 too much.

24 [Laughter]

25 But it would certainly make other studies easier.

1 DR. GILMAN: That is an honest answer. Dr. Kawas,
2 we didn't explore your thought about nimodipine.

3 DR. KAWAS: I think from an ethical perspective,
4 nimodipine has to be used in the studies.

5 DR. GILMAN: At all grades?

6 DR. KAWAS: Yes.

7 DR. GILMAN: Dr. Lacey?

8 DR. LACEY: My response is no. I feel there needs
9 to be replication of the studies on men, and there needs to
10 be replication regarding findings on women. So it has to
11 include both women and men. What I have seen so far suggests
12 that the neurogrades IV and V are more promising but I am
13 certainly open to it being all grades.

14 On the issue of women, of course as I have
15 expressed, I don't know that there is any support for it but
16 I do feel that treatment should be examined by stage of
17 ovulation of women.

18 DR. GILMAN: You mean whether ovulating or not?

19 DR. LACEY: Yes.

20 DR. GILMAN: Thank you. Dr. Lacey, do you want to
21 comment on the nimodipine issue?

22 DR. LACEY: I already commented about the FDA
23 looking at what is in the literature and everything. So, I
24 would echo what I said already about that.

25 DR. GILMAN: Thank you. Dr. Van Belle?

1 DR. VAN BELLE: No, and I think the important
2 thing would be to come to some agreement between the FDA and
3 the sponsor, if a future study were to be done, about what
4 the appropriate outcome is. In these reports you always get
5 a bit of a feeling that one group says one thing and the
6 other group says another thing, and if there were some
7 agreement a priori as to what the game plan is and what the
8 ground rules are it might save us some time as well. With
9 respect to nimodipine, I have no opinion.

10 DR. GILMAN: Dr. Grotta?

11 DR. GROTTA: As the data were presented and as I
12 have seen them, no, I am not persuaded, but I am
13 semi-persuaded that there may be in effect in all
14 subarachnoid hemorrhage subgroups if they were properly
15 dosed. So, I too would like to see another trial done in
16 both men dosed at 6 mg and women dosed at 15 mg, patients
17 treated within 24 hours compared to standard care. I would
18 stratify patients between those that are a Glasgow Coma
19 Scale of 9 or higher versus those less than 9, or using some
20 other easily applied measure, so that if you saw an effect
21 in the severely affected patients you could recognize it
22 with certainty.

23 But if the company decided to do just a study in
24 poor grade women and came up with a very positive study,
25 then I probably would be persuaded that that would be

1 enough.

2 DR. GILMAN: Thank you. Dr. Brooke had to leave,
3 as you know, but he has left a statement so I will simply
4 read it into the record: For question one, has the sponsor
5 demonstrated effectiveness? No. The sponsor has claimed an
6 effect of the drug on mortality. I have two serious
7 misgivings. One, the methodology of the trial and its
8 interpretation is marred by changing primary endpoints and
9 retrospective analyses. Although the results are intriguing,
10 they do not convince me that this drug should be approved.

11 Two, prolonging life without improving function in
12 the severely disabled may not be a useful or humanistic act.
13 Then he quotes, no, thou shalt not kill but neither shall
14 thou strive officiously to keep alive. I am sure he would
15 have read it better than me. Prolongation of life is better
16 justified when quality of life is improved. The sponsor has
17 not demonstrated any effect on function and has selected a
18 target group which is very severely disabled.

19 So, I don't think we need a vote but there are
20 eight of us and all have voted no to question number one.
21 Question number two --

22 DR. KATZ: Question number two presupposes really
23 in a sense that question number one would have been voted
24 yes. In other words, you can discuss whether or not you
25 think there is some overwhelming safety concern that we need

1 to pay attention to, but if you have found that there is no
2 substantial evidence of effectiveness safety is sort of a
3 moot point, at least from a decision-making point of view.

4 DR. KAWAS: I would just say I at least personally
5 have no overwhelming safety concerns either.

6 DR. GILMAN: Do you want us to go around the table
7 and get a sense of whether there are concerns from the
8 group? Let me lead off and say that there has been some
9 concern about the quality of data presented to the agency
10 with respect to safety. We heard from Dr. Racoosin that it
11 was rather difficult to read the records and understand
12 exactly what had happened to these patients, and I think the
13 quality of the data reported back is an issue, and another
14 study, hopefully, would have a better mechanism of reporting
15 those data or perhaps more full and complete records and
16 final diagnoses and autopsy verification when there were
17 autopsy studies done.

18 I think the question has been raised as to whether
19 there is a significant safety issue here, and I think the
20 question is open, myself. I am on the fence about that. Dr.
21 Drachman?

22 DR. DRACHMAN: I am not clear on it. No major
23 safety issue but data are not really sufficient.

24 DR. GILMAN: Dr. Kawas has commented. Dr. Penn?

25 DR. PENN: I don't have anything different to say.

1 DR. GILMAN: Dr. Lacey?

2 DR. LACEY: Nothing different than what has been
3 said.

4 DR. GILMAN: Dr. Van Belle?

5 DR. VAN BELLE: The same thing.

6 DR. GILMAN: Dr. Grotta?

7 DR. GROTTA: Nothing to add.

8 DR. GILMAN: All right, is there anything further
9 that the agency would want from us? If not, let me thank the
10 committee. Thank you all. We are adjourned.

11 DR. KATZ: I want to thank the committee also. It
12 was a lot of work; two long days. I appreciate it very much.
13 I would also like to thank Dr. Titus and her staff for
14 arranging this and making this run smoothly.

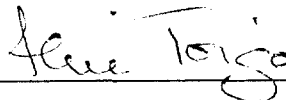
15 [Whereupon, at 4:00 p.m., the Committee was
16 adjourned]

17 - - -

18

C E R T I F I C A T E

I, **ALICE TOIGO**, 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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ALICE TOIGO

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