

1 DR. GILMAN: Well, the dosing regimen was
2 different. We are told it was in the ball park of 12.

3 DR. KATZ: But it was given every month. It's a
4 much shorter--

5 DR. GILMAN: That's right, that's right.

6 DR. WOLINSKY: If I could come back and reiterate
7 what I said before, I think it is conceivable--but we don't
8 have this data--it is conceivable with the aggressive dosing
9 that was done in the French study, possibly for a less long
10 period of time, that one conceivably could get the same
11 results, but we just don't know that. So in that sense,
12 voting or not voting, I think the data we have before us
13 certainly gives us some feeling for what the limits of
14 dosing ought to be.

15 DR. GILMAN: Does anybody else--voting members--
16 want to make a comment about that question that Dr. Katz has
17 posed?

18 Dr. Kawas?

19 DR. KAWAS: I just want to say I wouldn't have a
20 clue what would be the best dose to give a patient of this
21 drug or the frequency with which to give it. And even
22 though I am convinced that there is probably a clinical
23 effect of this drug, I think there is a lot of question
24 about the dosing and the frequency--a lot of question.

25 DR. GILMAN: Dr. Temple?

1 DR. TEMPLE: There is no doubt about that. I
2 can't imagine that by the time people who haven't yet been
3 treated roll around to the end of their 2 years, we can't
4 have reasonable data on what happens if you continue
5 therapy, and I'm sure we'll make sure that those data are
6 collected. So that at least ought to be known. Either you
7 do really have to stop at 140, or you don't, and we don't
8 know the answer to that yet. And it's not exactly
9 undiscoverable. There are people who must be approaching
10 that dose now who can be studied.

11 DR. PENN: It sounds like the usual FDA thing of
12 wanting to kill the dog to make sure you know where the
13 toxicity is, and I'm not sure that the company will be
14 overjoyed at running studies over 140, so I'm not sure
15 that's going to really get done.

16 The question of the exact dose, we can never
17 answer. It would take many studies to try to do that.
18 That's why they had their Phase I and II, to make a guess.

19 DR. GILMAN: Dr. Grundman?

20 DR. GRUNDMAN: Just going back to the EDSS scores
21 on M-38, you know, the Mitoxantrone at 5 mg had a more rapid
22 and more consistent effect than the Mitoxantrone at 12 mg,
23 and we don't have data on the MRI on the Mito-5 in the
24 second study.

25 DR. GILMAN: That is absolutely correct. Again,

1 the sponsor's aim was to use 12, and they wanted to use 5
2 just to see whether there was a greater effect at 12 than at
3 5.

4 DR. GRUNDMAN: There was.

5 DR. GILMAN: Well, for that one marker, there was
6 not.

7 DR. GRUNDMAN: The other markers were unblinded.

8 DR. GILMAN: Correct. But we've dealt with that.
9 We simply don't know the answer to that.

10 DR. TEMPLE: No--there was a better effect on two
11 of the other blinded markers--somewhat better. It wasn't
12 all that different, but it was leaning.

13 Just as an observation, the third-year data from
14 24 to 36 months, if I read it correctly, showed that people
15 began to get worse again; they didn't lose the entire
16 effect, but the trend lines if you were to draw them showed
17 that the disease started to recur, progression started to
18 recur, or whatever the right word is.

19 It is hard for me to imagine that people won't be
20 interested in knowing whether they could prevent that. We
21 don't know the answer yet, but wouldn't that be interesting?

22 DR. WEINER: I think that what you're going to see
23 happening is that one will try to prevent that by using
24 other drugs at that time rather than by using more of the
25 Mitoxantrone is what I would predict.

1 DR. GILMAN: Dr. Grotta?

2 DR. GROTTA: Well, in struggling to try to compare
3 the two studies, if you look at Table M-40 and Table M-64,
4 they both look at the same--admittedly, the patients are
5 different in the two studies--but they look at the
6 percentage of patients who change more than or equal to one
7 point on the EDSS, which to me is the most understandable
8 outcome. That is Number 40 and 64. And to me, what you are
9 trying to prevent is worsening, so if you look at the
10 percentage of patients who worsened in the Mito-12 category
11 in 901, it was 8 percent compared to 25 percent in placebo,
12 and in 902, it was 5 percent in the Mito plus
13 methylprednisolone versus 29 percent in placebo.

14 Clinically, at least, they are roughly comparable,
15 and I don't think we have enough information to say that one
16 is better than the other--although you are quite right--
17 maybe it is better to front-end-load it, but again, that's
18 not the question we're being asked, and I don't really see
19 that much of a difference to say that we shouldn't be at
20 this point approving the dose that is requested.

21 DR. WOLINSKY: Those two tables, of course, have
22 very different time lines.

23 DR. GILMAN: Exactly. One was monthly dosing, the
24 other was three-monthly dosing. Six months versus 2 to 3
25 years total duration of study. So I'm not sure they are

1 comparable at all. All right.

2 Again, I have to ask Dr. Temple, Dr. Katz, are
3 there any other question you want us to address, because we
4 are going to come to the question about requested approval.

5 DR. KATZ: One more which has to do with the fact
6 that all the studies were done in Europe, and there were no
7 domestic studies. I'd just like to know if people think
8 that's okay, if patients are the same, the standard of care
9 is pretty much the same, and the results in these studies
10 would be relevant and transferrable to the domestic
11 population.

12 DR. GILMAN: I don't personally see a problem with
13 that. It appears that Study 901 was well-designed. There
14 was some unblinding that I think could have been done a bit
15 better, that is, inappropriately unblinded aspects to the
16 study, but it looks as if the scales used were the scales
17 that would be used in this country, except for SNS. We did
18 not hear about validation of that scale. I can't really
19 comment on it, but it has been used in Germany for 10 years,
20 we hear. I don't think any of us around this table has a
21 bit of experience with it, anyway--or do we? Does anybody
22 have experience with the SNS?

23 [No response.]

24 DR. GILMAN: No. But to answer your question, I
25 am pretty comfortable with it.

1 Anybody else?

2 DR. WEINER: I would echo that. I am comfortable
3 with it.

4 DR. GILMAN: Anything else, then? Dr. Katz, Dr.
5 Temple, anything else?

6 DR. KATZ: No. Thank you.

7 DR. TEMPLE: No.

8 DR. GILMAN: All right.

9 The sponsor now requests approval for the
10 following: To slow progression of neurological disability
11 and reduce the relapse rate in patient with progressive
12 forms of multiple sclerosis, excluding primary progressive
13 multiple sclerosis.

14 So the question that we are asked--that is, the
15 voting members of the Committee--is: Has the sponsor
16 submitted substantial evidence of effectiveness to support
17 their proposed indication?

18 Members of the Committee who are going to vote on
19 this are Drs. Kawas, Penn, Van Belle, Grotta, Lacey, Penix
20 and Gilman.

21 I think there ought to be a bit of discussion to
22 lay the groundwork for our vote.

23 Dr. Grotta?

24 DR. GROTTA: I assume that our vote does not
25 necessarily endorse this exact wording, but rather the

ah

1 spirit of the wording according to the discussions we have
2 had?

3 DR. GILMAN: Precisely, yes. They will alter the
4 wording for the package insert if we are in approval, but
5 there are two points to this. One is the relapse, and the
6 second is disability, slowing the progression of
7 neurological disability. We could take them separately if
8 anybody wishes to; I think we could take them together
9 myself.

10 DR. KAWAS: Just in terms of the spirit, I planned
11 on voting no for that question, because as it is worded, I
12 feel very uncomfortable with it. As a neurologist who
13 doesn't take care of MS patients, but I think the average
14 neurologist would interpret it as it is worded right now for
15 a different form the disease to do something for patients
16 differently than the drugs that are currently available, and
17 although I do believe there is evidence of effectiveness of
18 this drug, it is not clear to me personally that it does
19 anything or provides anything other than an additional
20 armamentarium to the neurologist.

21 So how this is worded is very important to how I
22 would vote, and maybe I need to have a better idea than what
23 we are really being asked now with Question Number 1 as
24 opposed to Question Number 2.

25 DR. GILMAN: Would it help you if we separated the

1 two parts--to slow the progression of neurological
2 disability, talk about that, and then talk about reducing
3 the relapse rate?

4 DR. KAWAS: No. Probably the two parts that
5 bother me the most are I don't like "slow the progression of
6 neurologic disability," but I also don't like the
7 "progressive multiple sclerosis" term. As you have heard
8 today, I think a lot of people interpret that as a different
9 form of disease that provides a completely new indication,
10 whereas the drugs that are available don't do that.

11 DR. GILMAN: How would it sit with you if we said
12 "to slow worsening of neurological disability," et cetera,
13 "with worsening forms of multiple sclerosis"?

14 DR. KAWAS: That's getting better.

15 DR. PENN: I like it as it is for the reasons I
16 have said, but I don't know how everybody else feels about
17 it.

18 DR. GILMAN: We could go around the table and see
19 what people think.

20 DR. GROTTA: I'd recommend we take a vote on how
21 it is, and if it doesn't pass, then maybe we can wrestle
22 with amendments.

23 DR. GILMAN: Yes. It's going to be wordsmithing,
24 then, which I am a little bit uncomfortable with here.

25 Dr. Temple?

1 DR. TEMPLE: Obviously, people think the term
2 "progression" carries extra freight, and we don't have to
3 use that term. "Worsening" is fine, if that general idea
4 sounds better to people. And I think we are totally
5 convinced that the term "progressive multiple sclerosis" is
6 ambiguous, so we could substitute "worsening" and put in
7 parentheses the two subtypes, which as I understand it--tell
8 me where I am wrong--are secondary progressive MS or
9 relapsing remitting with worsening, or something like that.

10 That describes the population. It doesn't carry
11 any implication about what you are doing at the micro or
12 histologic level; it just says, I would have thought, what
13 was shown, if that's in fact what you think has been shown.

14 DR. GILMAN: I tend to agree with that. It is
15 close to the data, so I like that wording.

16 Dr. Grotta?

17 DR. GROTTA: In that case, I had written up a
18 slight amendment if you want me to read it.

19 DR. GILMAN: Go ahead.

20 DR. GROTTA: "To slow accumulated neurological
21 disability and reduce the relapse rate in patients with
22 clinically worsening, secondary progressive or relapsing
23 multiple sclerosis."

24 DR. GILMAN: It should be "relapsing remitting";
25 right?

1 DR. GROTTA: All right. Close, but no cigar.

2 DR. GILMAN: Right. We are wordsmithing. Could
3 we have that again?

4 DR. GROTTA: "To slow accumulated neurological
5 disability and reduce the relapse rate in patients with
6 clinically worsening, secondary progressive or relapsing
7 remitting multiple sclerosis."

8 DR. TEMPLE: The only thing wrong with that is
9 that relapsing remitting comes in two flavors.

10 DR. GROTTA: Well, "clinically worsening,
11 secondary progressive or relapsing remitting multiple
12 sclerosis."

13 DR. TEMPLE: Gotcha.

14 DR. WOLINSKY: What I think was studied in these
15 trials are patients with relapsing remitting and secondary
16 progressive disease with rapidly accumulating deficits.

17 DR. GILMAN: How rapid is "rapid"?

18 DR. WOLINSKY: The trials actually define that.

19 DR. KATZ: Again, my view would be that the use of
20 a modifier like "rapidly" is really open to interpretation,
21 even if in the clinical trials section of labeling we
22 actually say what the data are. My personal view would be
23 to stay away from that sort of language.

24 DR. PENIX: I like this modification. It does
25 help clarify the point somewhat. But there should be some

1 leeway. Physicians and patients should have some--we can't
2 characterize the intensity of the disease, so I think that
3 if we got rid of that "rapidly progressing," or did not
4 include that--in other words, I support Dr. Grotta's
5 amendment.

6 DR. GILMAN: Yes, I think it helps very much
7 myself.

8 Are there any other comments about that?

9 Dr. Temple?

10 DR. TEMPLE: Just to get your words right, would
11 you say the very first part of the sentence again?

12 DR. GROTTA: "To slow accumulated neurological
13 disability"--

14 DR. TEMPLE: Okay. I have a question. Do you
15 slow accumulated neurological disability, or do you reduce
16 it? You slow worsening--

17 DR. GROTTA: I'll defer to the group.

18 DR. WEINER: You could say "slow the accumulation
19 of"--that's what you're saying.

20 DR. TEMPLE: Well, it starts to get a little
21 complicated, but I think we could work on that.

22 You like the term "accumulated neurological
23 disability" in preference to "worsening neurological
24 disability"--there is a preference there?

25 DR. GROTTA: We are using "worsening" later in the

1 definition because we're seeing clinical worsening, and Dr.
2 Wolinsky proposed that what we are really doing--it's the
3 amount of neurologic disability that accumulates as a result
4 of their disease that we are either slowing or preventing.
5 I think the drug does seem to slow it. The rate of
6 development of the neurological deficit seems to be
7 retarded. Now, the question is it permanently retarded or
8 not, we don't need to address in this, but it does seem to
9 slow it.

10 DR. TEMPLE: Okay. I'm just checking. You like
11 the concept of "accumulated neurological disability" as
12 opposed to "worsening neurological disability"--I realize
13 the inelegance of using the same word twice in the same
14 sentence.

15 DR. GILMAN: What does "accumulated" mean, though?

16 DR. TEMPLE: Don't ask me.

17 DR. GILMAN: That's a serious question.

18 DR. GROTTA: Well, again, if somebody has visual
19 loss, hemipareses and ataxia, they are accumulating a number
20 of different neurological deficits, so it doesn't prevent
21 any one of them. In total, your score tests the global
22 function of the patient, and you are preventing their
23 disability. That's obviously only one way to say it, and if
24 someone has a better suggestion--but it seems to me
25 "accumulated neurological"--

1 DR. GILMAN: I think the problem is that you're
2 saying there is an accumulation of different systems into
3 the mix. But what about the patient who simply has a
4 worsening EDSS because the gait becomes worse and worse and
5 worse--is that still "accumulating"? Why not just
6 "worsening," so that you can get around this equivocation or
7 lack of clarity?

8 Dr. Katz?

9 DR. KATZ: Yes. I have a pretty good sense, I
10 believe, even though no vote has been taken yet, of what the
11 Committee thinks the drug does and what the data don't speak
12 to. I have worded the question this way to get the
13 Committee's sense of what you think the drug does, and I
14 think I have that sense--I think we have that sense.

15 If you would permit us, we can work on language
16 with the company and I'm sure we can come to some mutual
17 agreement, incorporating your views about what you think the
18 drug does. So if you just want to vote to say if there is
19 substantial evidence for a reasonable claim for MS or some
20 generic language, I'd be happy with a vote on that, and
21 we'll work on the language, the specifics, if that meets
22 with your approval.

23 DR. GILMAN: Approved.

24 DR. WEINER: I would just like to make a comment.
25 I don't know the name of the doctor sitting right next to

1 you--

2 DR. GILMAN: Dr. Kawas.

3 DR. WEINER: --yes--I would also support some of
4 the comments that you made in the fact that this is not
5 something unique to progressive MS that has never been shown
6 before per se, but I support some of your comments.

7 DR. GILMAN: Well, all the same, I think we should
8 take a vote. If the voting members of the Committee are
9 comfortable with what we just heard from Dr. Katz, it will
10 be something close to what Dr. Grotta said. I would prefer
11 not to have the word "accumulating" in there, because that's
12 not clear to me, but if it is "worsening," all right.

13 Is there any further discussion, or shall we vote?

14 [No response.]

15 DR. GILMAN: All those in favor--there should be
16 seven votes--the question is has the sponsor submitted
17 substantial evidence of effectiveness to support their
18 proposed indication, and the proposed indication is as
19 modified, as we have discussed--"worsening of neurological
20 disability," et cetera. All right?

21 All those who say yes, the sponsor has submitted
22 evidence, please raise your hands.

23 [A show of hands.]

24 DR. GILMAN: So it is unanimous.

25 Let's move on, then. If not, then--well, we have,

1 so we can drop Question 2.

2 Question 3: Has the sponsor submitted sufficient
3 safety data?

4 In my view, yes, but let me hear from the rest of
5 the Committee and from our consultants.

6 DR. WEINER: I would say yes.

7 DR. WOLINSKY: Yes. I think they have convinced
8 me that they will do a good job in limiting us.

9 DR. GILMAN: Committee members, any discussion of
10 this?

11 DR. KAWAS: Once again for me, at least, the
12 wording is very important. I think it is crucial that
13 additional data is collected even if this drug were approved
14 and available, in post-marketing and other ways. I feel
15 that there are a lot of questions that haven't been answered
16 yet in terms of safety in the long run and maintaining
17 dosage.

18 This drug looks to me like it does what other
19 drugs available for MS do, but the toxicity looks to me like
20 it has the potential to be greater in the long run, and we
21 won't know that without looking further.

22 DR. GILMAN: Can you elaborate a little on some of
23 your concerns? You said long-term safety data--is that what
24 you are referring to--say, 5 years' experience. We did hear
25 about some accumulated data over 10 years or so.

1 DR. KAWAS: Primarily my concern would be over a
2 long duration and high-dose usage, yes.

3 DR. GILMAN: Could you define "long duration"?

4 DR. KAWAS: We have seen data when this was
5 administered over 2 years, and I guess, presumably, that's
6 what would be recommended. And I guess, presumably, it
7 would also be recommended that nobody get another course of
8 this ever again. I mean, people with MS have MS when they
9 are 20, and they still have it when they are 40 and when
10 they are 60 and when they are 80, and we don't have any way
11 of knowing whether or not additional dosage regimens or
12 anything like that is appropriate. Everybody knows that
13 physicians kind of so whatever they want, in spite of what
14 is on the package insert, and I think it would be very
15 useful to have an idea of what would happen if they gave
16 another dosage to this.

17 The one patient who received two regimens of this
18 of 155 mg cumulative and 120 mg was a 40-year-old who were
19 are told died.

20 DR. GILMAN: Dr. Penix?

21 DR. PENIX: The representatives of Immunex have
22 indicated that they would, but I would certainly like to see
23 a specific cap set and also some guidelines about patient
24 monitoring, in specific, both in regard to the cardiac
25 function and in regard to the hematologic monitoring.

1 DR. GILMAN: Are we ready for the vote? All
2 right.

3 All those who believe the sponsor has submitted
4 sufficient safety data of the voting members, please raise
5 your hands.

6 [A show of hands.]

7 DR. GILMAN: Six.

8 All those who do not believe that sufficient data
9 on safety has been submitted?

10 [One hand raised.]

11 DR. GILMAN: One. One opposes that notion.

12 Now, are there any other questions that the
13 Division wants us to address? Dr. Katz?

14 Dr. Kawas?

15 DR. KAWAS: Actually, maybe it's an extension of
16 the safety issue, but I thought the Division also asked us
17 to consider whether there should be restrictions on the way
18 the drug was given out and by whom.

19 DR. GILMAN: Thank you. Yes, they did. The
20 question is whether this drug should be administered by
21 oncologists only, or should neurologists who have license,
22 essentially, have the capacity to give it.

23 Dr. Penn?

24 DR. PENN: I was hoping you would include
25 neurosurgeons in this category. I think it is a danger to

1 give specific information like that, to restrict the drug in
2 that way, and it depends on the education of the doctors who
3 do it. I think that if the company puts an emphasis on
4 education, then there are a great number of people who could
5 potentially use this safely--even nurse practitioners, if
6 you don't mind my saying so.

7 DR. GILMAN: I would tend to agree that, really,
8 it depends upon the education, sensitivity, knowledge base,
9 and care of the treating physician, not necessarily how that
10 person has been boarded, as it were, but let me hear the
11 other members of the Committee talk about that.

12 Dr. Penix?

13 DR. PENIX: I agree. I think that perhaps people
14 are concerned about the lack of treatable diseases that
15 neurologists have taken care of. But clearly, in our
16 experience, the MS physicians are dedicated and have a great
17 deal of experience in taking care of these patients and also
18 will be primarily responsible for following their clinical
19 outcome. So I think there should not be any restrictions.

20 DR. GILMAN: Is that unanimous?

21 Dr. Kawas?

22 DR. KAWAS: I think it's a mistake to say that
23 this is going to be given out by MS physicians. I mean,
24 most of us around this table come from academic centers, so
25 we get into this notion of thinking that every doctor takes

1 care of only one disease. But the majority of this is going
2 to be given out by people who are a little more broad than
3 that, including internists and other doctors.

4 I'm not so sure that I would suggest a restriction
5 based on specialty, however, but how about some kind of
6 registry restriction? I believe, for example, there is a
7 precedent with Clozaril where anybody who goes through the
8 paperwork or whatever potentially can distribute the drug,
9 but going through the paperwork ensures an education
10 process. Is that an option that perhaps we should be
11 considering?

12 DR. GILMAN: Dr. Temple--that's something that the
13 FDA will address, I suspect.

14 DR. TEMPLE: Yes, we'll explore that. A recently
15 approved anti-arrhythmic drug that has to be started in the
16 hospital is available only to people who have taken the
17 training program. One of the difficulties is that this is a
18 drug that is out there for other uses, and it is not so easy
19 to do that, because it can be prescribed through those other
20 forums.

21 But we would certainly think about what kind of
22 training, special packaging, et cetera, would be appropriate
23 here.

24 DR. PENIX: My impression is that with Clozaril
25 and maybe some of the other anti-arrhythmics, the concern

1 there is because of the potential fatal outcomes, and it
2 appears that there is no increase in fatal outcome with this
3 particular drug. That may require--my vote would be not to
4 limit it, and I hope I didn't imply before that there should
5 be specialty limitations, because I don't think so.

6 DR. GILMAN: Dr. Lacey, please.

7 DR. LACEY: I would like to speak against limiting
8 the administration of the drug by specialty, based on the
9 geographic area in which I live as an illustration of many
10 areas of this country. In one-third of the State of
11 Illinois, the southern part of Illinois, there is often not
12 a single neurologist practicing.

13 DR. PENIX: Nor oncologist, probably.

14 DR. LACEY: No. We have oncologists sometimes,
15 but not a neurologist. So if you were restricted on the
16 side of neurologists--

17 DR. GILMAN: Dr. Kawas, do you want to comment
18 further.

19 DR. KAWAS: I guess I just wanted to say in part
20 the reason I voted no on do we have enough safety data is
21 because there were no fatalities in people who just got one
22 course under careful clinical observation. There was a
23 fatality of an individual who got two courses. The average
24 patient and his doctor--I mean, patients who live a block
25 from the hospital are told on a regular basis that they

1 cannot come and see me anymore. So I think we don't know
2 whether two courses of this disease will kill people or not.
3 So I guess all I want to put a plea in for is some mechanism
4 where that could be controlled.

5 DR. PENIX: Would not the cap on the total dosage-
6 -because the dose that the patient got who died, didn't it
7 exceed 140 mg?

8 DR. GILMAN: The patient got 275 mg.

9 DR. KATZ: I don't think--270 mg per meter
10 squared--but in any event, theoretically, in an ideal world,
11 the cap of 140, if that's what we ultimately decide on,
12 would do it. But as Claudia points out, people go to
13 different doctors; people move around, they want more, and
14 they will try to get more, and they aren't necessarily going
15 to tell their history. I don't know if this is going to
16 happen, but this is certainly one thing that presumably you
17 could be reasonably concerned about given what we think we
18 know about the toxicity at even minimally higher doses than
19 140.

20 DR. GILMAN: Dr. Grotta, then Dr. Penix.

21 DR. GROTTA: Well, my experience is that if you
22 put all these warnings and so on about side effects on the
23 package insert, physicians in this country, where there is a
24 lawyer on every corner, are not going to be prescribing this
25 drug unless they are very careful and cautious about it.

1 You can never totally safeguard against misuse of a drug if
2 someone doesn't pay attention, and I don't think we can do
3 that, so I think we just put the warnings and the side
4 effects on the package insert and the limitations of dose,
5 and that should be sufficient.

6 DR. GILMAN: Dr. Penix?

7 DR. PENIX: I agree with that. As a stroke
8 neurologist, in my experience, I have never seen anyone
9 exceed the recommended dose of Ticlopidine [ph.] nor TPA.
10 So I think if we put it on the package insert and make it
11 very clear, physicians would tend not to do that. But
12 you're right, there is a complication of patients not
13 reporting it to the physicians, and I think that that is
14 going to be impossible to regulate.

15 DR. GILMAN: Do you want a vote on this question,
16 Dr. Katz, or have you heard enough--

17 DR. KATZ: I have heard enough.

18 DR. GILMAN: Would you like to hear anymore about
19 anything else--Dr. Temple, Dr. Katz?

20 DR. KATZ: No. The only thing I have left to say
21 is to thank everybody. It has been a long day, with a lot
22 of difficult issues, and I think everybody really
23 contributed, and I want to thank you very much.

24 I particularly want to publicly thank Drs. Kawas
25 and Gilman, whose last meeting this is, at least for a

1 while. They are rotating off the Committee. You have both
2 been tremendous assets to the Division and to the Committee--
3 -it goes without saying, but it is worth saying--you have
4 been courageous at times under very stressful conditions,
5 publicly, and I want to thank you very much. The Committee
6 will miss you, the Division will miss you, and I personally
7 will miss you. Thank you very much for your work.

8 [Applause.]

9 DR. GILMAN: Thank you, Dr. Katz, and let me thank
10 the Committee and consultants. It has been an interesting
11 day.

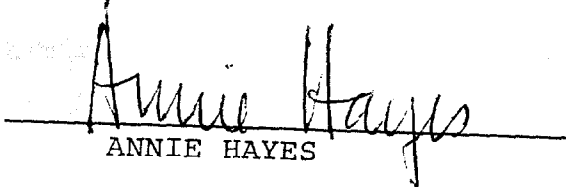
12 We will adjourn now.

13 [Whereupon, at 5:27 p.m., the proceedings were
14 concluded.]

15

CERTIFICATE

I, ANNIE HAYES 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.


ANNIE HAYES

Lawyer's Notes

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0 62:21; 107:2; 173:1
0.0001 50:18
0.0002 52:7
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