

1 treatment, for example, of pregnancy, imprisonment,
2 and so on.

3 The next slide. This slide just shows
4 that if you have treatment discontinuation that is
5 unrelated to the treatment if it happens kind of
6 equally with equal trends in both treatment arms and
7 you are going to dilute your effect, then you will end
8 up with lower power than if you used the virologic
9 failure alone. Even though you get more endpoints
10 from the composite, you end up with less power, in
11 this particular example reducing from 80 to 60
12 percent.

13 I will skip the next slide, which is just
14 illustrating that point, and go on to the factorial
15 design of 359, which Trip Gulick just mentioned. He
16 was the chair of that study. He described the
17 randomization factorial between ritonavir and
18 nelfinavir and then between delavirdine, adefovir, or
19 delavirdine plus adefovir.

20 The results graphed in this way showing
21 the proportion below detection for the different arms.
22 And, as John Mellors noted earlier, your power to
23 compare any individual cell with any other cell is
24 much lower than if you had just done a two-arm study,
25 but you can look at the different factors in the next

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1 slide. This is for comparing ritonavir and
2 nelfinavir. And in the next slide, the comparisons
3 between delavirdine, adefovir, and delavirdine and
4 adefovir alone.

5 Next slide. You can also, of course, look
6 at the mean HIV RNA change from baseline in this slide
7 displaying all of the arms. One of the interesting
8 questions is: How much more power do you get from
9 using change in HIV RNA compared to proportion below
10 detection? Obviously the change should give you more
11 information. There should be more power.

12 Next slide. This slide just shows that
13 there were actually more than 90 percent of patients
14 that have 16-week data. The messiness was scattered
15 over the arms a little bit more in the ritonavir.

16 Next slide. This comparison, as I think
17 Trip has already shown, shows once again that when you
18 compare ritonavir and nelfinavir, you don't see a
19 difference, but comparing over the arms in the other
20 factor, you do see a significant difference.

21 Then in the next slide, if you do the same
22 tests on the median change from baseline, it was
23 interesting. You get pretty much the same message.
24 Of course, ritonavir versus nelfinavir is not
25 significant.

1 And here the group gets slightly different
2 comparisons. Rather than comparing across each of the
3 comparing across all of the three levels of the
4 delavirdine-adeфовir factor, they did the comparisons
5 individually.

6 What was interesting is that you do see
7 the significant difference between delavirdine and
8 adefовir, not significant difference for the other
9 ones. Overall there didn't seem to be a lot of
10 difference in the message; in fact, none at all, that
11 you would get between looking at a proportion below
12 detection or a change from baseline. So I think it
13 would be very useful, in fact, to be able to look at
14 both of those and just look for consistency.

15 This study shows results of AIDS Clinical
16 Trials Group Study 364, in which patients received two
17 nucleosides and randomized to nelfinavir alone,
18 efavirenz alone, or the combination.

19 This slide shows the results with the time
20 to virologic failure. And, interestingly, all of the
21 comparisons, both the three-way comparisons across all
22 the arms in each individual comparison, showed a
23 statistically significant difference.

24 In the next slide, if you looked at a time
25 to virologic failure or stopping the step one

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1 treatment, that was not an endpoint in the study. We
2 just did this analysis to try and investigate what
3 would happen if you used different kinds of endpoints.

4 What is interesting here is that you see
5 the same ordering of the arms, but the comparison of
6 efavirenz versus nelfinavir plus efavirenz, that's the
7 comparison that's at the bottom here. I don't know if
8 folks can see that. It is non-significant in this
9 case.

10 So it is interesting that, once again, you
11 get more endpoints with the time to virologic failure
12 or stopping the treatment, but you end up with
13 actually a nonsignificant comparison, which was in the
14 other endpoint.

15 The next slide gives some illustration
16 why. The curve that is in red there refers to the
17 patients that got nelfinavir plus efavirenz. And,
18 although 12 of those patients actually stopped
19 treatment -- that was the highest number that stopped
20 treatment, only 2 of them actually experienced
21 virologic failure. The curve drops more because of
22 the number of people in the risk set.

23 So I think that these kinds of
24 investigations can be useful in looking at salvage
25 trials or any trial. If virologic failure is the

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1 primary endpoint, it is probably the most informative,
2 but it may be interesting to look at the time to
3 stopping the treatment or virologic failure and then
4 investigate what happened to the people who stopped
5 treatment.

6 Now, a big issue that has come up
7 frequently in this and other settings is: What do you
8 do about losses to follow-up? Well, the first point
9 that you need a policy for handling them is pretty
10 obvious.

11 If you treat a dropout as either censored
12 or treat it as failed, either result can be biased.
13 So one of the approaches is to do both of them and see
14 whether it makes a difference.

15 And then I think it is also going to be
16 increasingly important to do sensitivity analyses to
17 try to investigate the robustness of the results that
18 you get to different assumptions about how and why
19 patients dropped out.

20 The next slide. This is just hypothetical
21 data that Camlon Tierny generated and just showed an
22 example, a hypothetical study, where you get a
23 treatment effect comparing A to B.

24 Then in the next slide, what we see is the
25 same study where half of the patients had equal risk

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1 of dropping out at any time point in the study. And
2 what you see, of course, is you lost power. There is
3 no significant effect.

4 And then in the next slide, the next slide
5 shows the case where -- well, in the previous slide,
6 we had independent censoring. It had nothing to do
7 with the treatment assignment. In this case, for the
8 curve that is in red, we have an example where one arm
9 experienced more loss to follow-up than did the other
10 arm. So the treatment did lead to a difference in
11 losses to follow-up. And obviously you can get a
12 strongly biased effect in this case and p -value of .9
13 that is not at all significant.

14 Then, to show an example of a study in
15 which different approaches to missing this were
16 actually -- to handling missing this and dropping out
17 were actually taken and what impact it had to protocol
18 398 that Trip Gulick already introduced.

19 In this arm, all of the patients received
20 amprenavir, abacavir, efavirenz, or adefovir. And
21 then patients were randomized to receiving on top of
22 that either saquinavir, indinavir, or nelfinavir.

23 And in the next slide, the design of the
24 study. These are the actual numbers that enrolled,
25 the patients, but the kind of ideal that was proposed

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1 at the start.

2 The randomizations depended on the
3 experience, the prior experience, that the patient
4 had. So, for example, patients who had already been
5 exposed to saquinavir were not randomized to
6 saquinavir again but only to either indinavir,
7 nelfinavir, or placebo. And, of course, if it were a
8 new drug you were investigating, you could have,
9 instead of the placebo, put the new drug in that
10 particular slot.

11 Then the next slide, I think Trip has
12 already shown some of the results from protocol 398.
13 It appears as though in this slide, which looks at the
14 median changes from baseline, the placebo arm had the
15 least median change from baseline.

16 Next slide. This slide looked at two
17 different ways of handling the missing data. The
18 column on the left is a missing equals failure
19 analysis. The column on the right is missing at
20 random assumption, MAR, treating the missing as
21 censored observation. And this was the estimated
22 virologic failure rate at week 24.

23 And, as you can see, that rate was quite
24 high across all the arms. But if you look separately
25 at the group that did not have NNRTI experience, the

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1 group that was getting their first NNRTI, the failure
2 rates were in general lower.

3 What was reassuring about this analysis is
4 it showed that, although the missing equals failure
5 has higher failure rates than the missing at random
6 assumption leads to, in fact, the patterns of failure
7 are very, very close between these two analyses. So
8 the inference is very much the same.

9 In the next slide, the study also did a
10 primary comparison of the proportion of the patients
11 whose RNA values were less than 200 at week 24,
12 showing kind of similar results.

13 And the final slide for 398, this slide
14 showed the p-values for two different analyses. One
15 was whether or not patients had a confirmed virologic
16 failure at or before week 24, the analysis on top.
17 The analysis on the bottom is for the time to
18 confirmed virologic failure. We don't see a lot of
19 difference. In fact, those two analyses are very
20 consistent.

21 Also, comparing missing equals failure and
22 missing at random were done. Once again, you get a
23 reassuring agreement in these analyses that if you
24 look at the left column, receiving a new protease
25 compared to placebo was a significant difference. And

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1 also the nelfinavir versus placebo was significant.

2 I should point out that there ended up
3 being a lot more patients randomized to nelfinavir
4 because of the patient population that entered. So
5 there was more power for that comparison than the
6 other ones.

7 In the next slide, we want to get back
8 briefly to the question of: If you're looking at a
9 change endpoint, a change from week 24, let's say, to
10 baseline and some patients either drop out in the
11 middle or they switch to another treatment in the
12 middle, how do you handle this situation?

13 One of the things you can do is carry the
14 last observation forward, but if the RNA curve,
15 schematically drawn in yellow here, is not flat but,
16 in fact, has this characteristic dip and rise, then
17 when you dropped out, it is going to make a big
18 difference.

19 So one of the ways of addressing this
20 issue is you might want to consider carrying the last
21 rank forward, rather than the last observation itself.

22 So, for example, if a patient dropped out
23 at one, two, or three in that case, although their
24 levels would be very different, the rank might not
25 change quite as much.

1 Then in the next slide, so, finally, some
2 discussion points. Should we count study withdrawal
3 as failure censored? Each one is likely to be
4 analysis. Recommend carrying out both and doing some
5 sensitivity analysis.

6 And then, the final slide, what are the
7 criteria for selecting the primary endpoint? Well,
8 obviously you want to select an endpoint that
9 addresses the primary objective, taking into account
10 patient population of the study drugs.

11 It is going to be very different across
12 different populations or it may well be different.
13 And within the possible pool of surrogate markers, try
14 and pick one that we believe to be the best possible
15 replacement for a true clinical endpoint, but I want
16 to strongly endorse what Mike Saag and others have
17 said today that we need cohorts, long-term follow-up
18 to find out how well these surrogates are really
19 doing.

20 I would add to what Mike said that
21 including in those cohorts longer-term follow-up of
22 people who have participated in a randomization would
23 be helpful as well.

24 ACTING CHAIRMAN GULICK: Thanks, Dr.
25 DeGruttola.

1 Are there clarifying questions for either
2 Dr. DeGruttola or me?

3 (No response.)

4 QUESTIONS TO THE COMMITTEE

5 ACTING CHAIRMAN GULICK: Okay. So our
6 last task this afternoon is to address two last
7 questions to the Committee, both concerning endpoints.
8 The first is: What are the most appropriate study
9 endpoints for trials in heavily pretreated patients,
10 comments on the strengths and weaknesses of virologic,
11 immunologic, and clinical endpoints? And, in
12 addition, discuss the relevance of virologic endpoint
13 metrics other than below the level of detection.

14 So let's stick to the first question, What
15 are the most appropriate study endpoints? Dr.
16 Mathews?

17 DR. MATHEWS: Bearing in mind we are
18 talking about pretreated patients, I think in my own
19 mind that we somehow need to include in the endpoint
20 both CD4 and viral load response. The reason I say
21 that is because of the accumulating data that people
22 are still experiencing clinical benefit.

23 You know, at one extreme, if the trigger
24 were rebound from baseline viral load or becoming
25 detectable again, in practice many people would not

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1 change the regimen, even if there were potential
2 options available for those patients, because they
3 might want to wait a while.

4 So if the real goal of the therapeutic
5 analysis is to determine clinical benefit and not some
6 arbitrary virological endpoint, perhaps we should
7 grapple a bit with: How do you integrate both CD4 and
8 viral load response? Do you have multiple endpoints
9 or sequential endpoints so that if a person met a
10 virological endpoint but had not yet met an
11 immunologic endpoint and had few options, they would
12 continue on therapy?

13 Another angle on this is if you're going
14 to look at binary responses, failure or not failure,
15 if you were going to integrate CD4 and viral loads, it
16 would not simply be binary. There would be perhaps
17 three or four categories of responses that would be
18 taken into account. And they could be ranked by their
19 prognostic value, which we're seeing accumulating
20 evidence from natural history studies that, in fact,
21 you do learn something from looking at these so-called
22 discordant responses.

23 ACTING CHAIRMAN GULICK: Dr. Eron?

24 DR. ERON: This is kind of more of a
25 question to Mike and Victor and others. We frequently

1 say things like "a half log change in viral load
2 connotates a clinical benefit" or "is likely to result
3 in a clinical benefit."

4 Of course, that has to be a half log
5 change at some time. I mean, two weeks it probably
6 isn't important. At 16 weeks, maybe it is. Do we
7 have a better handle on that? Are there algorithms
8 for both change in viral load and change in CD4 to try
9 to capture the clinical benefit, particularly from
10 some of the older studies?

11 DR. DeGRUTTOLA: I think that someone
12 alluded to one of the studies by Ian Marshener and a
13 group of us within the eighth Clinical Trials Group.
14 As I recall, that was looking at HIV RNA at the
15 exchange point, but it was in the era of the
16 nucleosides. I think it did show that a half log drop
17 was associated with better outcomes.

18 We haven't gone back and redone those
19 analyses in the modern era. So I think we should be
20 a little cautious about assuming that the same
21 relationships will hold with the currently available
22 drugs.

23 I think that those analyses should be
24 repeated. Maybe they have been, but I think we need
25 to see more of that.

1 ACTING CHAIRMAN GULICK: Dr. Murray and
2 then Mr. Hogan.

3 DR. MURRAY: I think the only data that
4 would illustrate when you should cut an endpoint, at
5 what time, would be maybe the Pharmacia, an Upjohn
6 endpoint that was presented at a 1997 committee, and
7 where a response was a half a log at least and that
8 they looked at days of response of a half a log at
9 least correlating with clinical benefit.

10 I think you really didn't get a
11 significant correlation until it was about greater
12 than eight weeks or so. So probably something less
13 than eight weeks.

14 In fact, in one of those studies, 017, I
15 guess, -- it was delavirdine added on to ddI -- there
16 was about a half a log difference between the arms,
17 but it only extended to maybe six to eight weeks. And
18 there was no difference in clinical benefit in the
19 treatment of raw.

20 When the studies were analyzed according
21 to days of response, something less than two months
22 didn't -- there's lots of data showing that 16 and
23 24-week changes of anywhere from .3 to .5 logs for the
24 group did correlate with some clinical benefit. And
25 we went through that data about three or four years

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1 ago but only one really analysis looking at the time
2 effect.

3 I guess I would like to probe the
4 combination CD4-HIV RNA endpoint because I guess in my
5 mind if I were interested in a drug to treat patients
6 who had been heavily treated, I would really be
7 looking for a drug that would have an antiviral
8 effect. If it didn't have an antiviral effect, then
9 how different is that than maintaining the status quo?

10 I mean, presumably the people who are
11 doing well on drugs who still have viral replication
12 are doing so because maybe they're maintaining
13 mutations and they're maintaining a less fit virus.
14 But do we need another drug just to maintain mutations
15 or less virus? Are we really looking for hopefully a
16 drug that would be a little bit more novel?

17 I would think, I would hope to have, drugs
18 that would be developed that would have an antiviral
19 effect in patients who had already received treatment.
20 And I think it would be pretty murky to interpret a
21 combination if there was no antiviral effect, to just
22 look at CD4.

23 ACTING CHAIRMAN GULICK: Mr. Hogan and
24 then Dr. Saag.

25 MR. HOGAN: Well, I think it's important

1 to recognize that a half log change in viral RNA is
2 sort of to cut off what's significant in an
3 individual, but in aggregate groups, much smaller
4 changes actually are meaningful. So as you have a
5 larger group of people, you get more precision in
6 that. And you've got a greater sensitivity.

7 I would love to be as optimistic to
8 believe that we're going to have therapies that are
9 going to have dramatic virologic effects in this
10 population. It's not clear to me, at least based on
11 what we in the lay community see coming down the
12 pipeline, that that is extraordinarily likely.

13 I do agree that trying to figure out how
14 to combine CD4 and viral load in a meaningful way
15 would be a Herculean task. I mean, just weighting the
16 two against each other, I wouldn't know where to
17 begin, but, as I said in my presentation, I do think
18 preservation of CD4 count may be possibly the most
19 relevant and the most achievable surrogate endpoint
20 that one could hope for. And certainly if you look at
21 the data, CD4 count is so much more predictive than
22 viral load.

23 Now, the caveat to that is in very low CD4
24 count people, that's not as true, but for your short,
25 intermediate-term risks, CD4 tells you so much more

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1 than viral load.

2 Lastly, I guess, I hate to stir up
3 controversy, but we don't really have a good grasp on
4 what the course of disease is in these, quote,
5 unquote, "deep salvage" patients yet. And, as people
6 are noting, they are seeing research in allies, and it
7 may be realistic to talk about clinical endpoint
8 trials.

9 ACTING CHAIRMAN GULICK: Dr. Saag?

10 DR. SAAG: I would like to go back to
11 maybe Jeff's point and sort of remind ourselves that
12 these are antiviral drugs and for the most part are
13 retroviral. So I think we ought to look at the
14 virologic activity.

15 What's interesting to me is that the 0.4,
16 0.5 log reduction is a factor or is a value that keeps
17 coming up over and over again, which sort of hints to
18 me that it might be important.

19 Let me be precise that 0.3 oftentimes is
20 just considered to be the variability in the assay, at
21 least in the old days. And so for us to have looked
22 at any drug early on, back when these drugs were first
23 being developed and viral load became available, 0.3
24 is what we wanted as a minimum to say that this is
25 different than just placebo or just some random

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1 effect. So the 0.5 is a minimal effect that you would
2 like to see.

3 The second thing is the Ian Marshener
4 study that Victor referred to. While I think there is
5 a possibility that it is class-specific, biologically
6 it's hard for me to understand why that would be.

7 So I think we ought to explore that, but
8 in the meantime I don't think it's such an
9 unreasonable assumption to say that biology is biology
10 and why should it be different based on the type of
11 drugs. You just get more of it. You get more of a
12 drop than .5. But it's possible that you might not
13 see the effect. It needs to be explored, but at least
14 that's a hint that that number might be important.

15 The third thing is work that Steve's group
16 has done as well as our group to maybe a more limited
17 degree that just looks at the sustaining of CD4
18 effect, even among people who have rising viral loads
19 coming back up, that the CD4 count does not seem to
20 drop until you cross that magical threshold of about
21 .4 to .5 log as you come back to the original
22 baseline. So I think that's a reasonable number just
23 to pick one. That's one I would put out.

24 And I think your point is right. If you
25 look at a population, that may be different, but I

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1 would flip it around and say I would take each
2 individual patient and say: Look at the time to
3 failure. And look at it from a Kaplan-Meier
4 survival-type thing in terms of time to failure. And
5 that's how you would define.

6 If at eight weeks you look and they're not
7 where you need them to be, they're a failure. They're
8 categorized as a failure. They move on to whatever
9 else, and that's the endpoint for that study. And if
10 they are below it, you just follow them out and see
11 how long they are out and then at the end of the day
12 what proportion of patients are below that target or
13 not for this population.

14 I think maybe the final point is one that
15 Judith Falloon said. I think this is exactly right,
16 and I don't know how to deal with this exactly. We
17 have to remember the people are coming into the study
18 on something usually. So, really, the .5 below
19 baseline, the baseline in my mind is really off
20 therapy. And if we could go back and find out what
21 their set point was, then you've got something that
22 you can hang your hat on.

23 Maybe it's worth a run-in off therapy. I
24 think it's a little bit hazardous. Somehow we're
25 going to be stuck with a decision of requiring in a

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1 study that we know what their set point was off of
2 therapy or determine it versus let that go and just
3 take whatever they are if we're defining them as,
4 quote, "failing" and hope that we can get .5 reduction
5 further from whatever they were on before.

6 If we're simply adding the drug, the new
7 agent, to the failing regimen, that's a legitimate
8 thing to look for .5 in a short period of time, like
9 that 10-day double hybrid monster thing we were
10 talking about, but for start changing the entire
11 regimen and adding or not, then it becomes a little
12 bit more problematic. And I think that is something
13 that we have to wrestle with.

14 ACTING CHAIRMAN GULICK: Dr. Schapiro?

15 MR. HOGAN: One clarification. One thing
16 which I don't think I expressed clearly was that that
17 .5 log is the variation in the individual and that as
18 you get larger groups, the variation becomes much
19 smaller. So that's what I'm saying. When I'm saying
20 need, what I meant was that variation.

21 The final thought which I didn't say
22 before I'll shoehorn in, I think it's very important
23 to recognize the increase in power in using non-binary
24 outcomes. And I think below quantification may not
25 only be unrealistic, but it's also less power than

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1 using something continuous.

2 ACTING CHAIRMAN GULICK: Dr. Schapiro and
3 then Dr. Mathews.

4 DR. SCHAPIRO: To specifically address the
5 question of Dr. Murray regarding combining CD4 and
6 viral load and taking into consideration what we heard
7 from Victor, I think combining is dangerous because we
8 do have a dilution effect. We're working very hard to
9 get our numbers up as high as possible, and then we're
10 doing things which are going to reduce our power.

11 What was not shown in many of these
12 presentations, for good reason, is the CD4 response.
13 VIRADAPT, GART, all of these studies, VIRA 301 many of
14 these, don't show any difference in CD4 cell.

15 When we do a comparative study, when we do
16 the descriptive studies, we love to show CD4s because
17 we show something. When you do these kinds of
18 presentations, myself and all of us, we tend to show
19 the viral load because they're more informed but,
20 actually, because there wasn't any difference in the
21 CD4s.

22 And the virology of this has I think been
23 described in many studies. It appears that any
24 reduction in viral load, I think, as Mike said, below
25 0.5, whether it's an 0.6 and 0.9 might not show over

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1 the same time period of CD4.

2 There's some suggestion from Steve's data
3 that might manifest way out there, but it's not going
4 to give a change here. If we add CD4 on, we're going
5 to get dilution of our viral load. So I would say
6 that in this population, I would say not to combine.

7 A second issue I would address is the
8 cutoffs. I think we made mistakes in the past.
9 Looking at some of these data, I think in Trip's
10 presentation, we saw that often there were very
11 disappointing results because we were using probably
12 the wrong endpoint.

13 Using cutoffs in general I think is a less
14 good idea. I also think that we should probably be
15 less trying to prove something than show our data.
16 Change in viral load is good, and we can later do a
17 lot of things with that.

18 My gut feeling would be that we should
19 show the change in viral load. That should always be
20 an endpoint. We can do other things with that later.

21 I would say splitting it, as opposed to
22 combining it. It is good to see as many endpoints as
23 we can to get the differences and not to get too
24 sophisticated with combining. I think we will get in
25 trouble there. I think we should try to keep it

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1 simple. And I think we should look at multiple.

2 And just one last thing. We should keep
3 in mind that all of these are regarding our standard
4 antiviral therapies. I think, for example, when we
5 started looking at maybe hydroxy area and I think
6 we're going to have other novel types of
7 interventions, we have to reconsider what we're
8 looking at. They may be working.

9 We would like to always know what is a
10 good surrogate for clinical endpoints. I think viral
11 load is very good with our standard drugs. When we
12 look at others, we should keep that in mind.

13 ACTING CHAIRMAN GULICK: Dr. Mathews?

14 DR. MATHEWS: Well, I don't want to see
15 the final nail put in the coffin of something other
16 than viral load as an endpoint. You know, this
17 morning already several other potential endpoints were
18 talked about which are virologic endpoints but aren't
19 viral load endpoints, such as resistance and fitness.

20 My major point on this is that if you're
21 talking about treating a particular population of
22 patients, the goal should be to find out what
23 treatments confer clinical benefit.

24 Clinical benefit certainly is not
25 completely summarized by a viral load response. I

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1 mean, we have seen lots of data, both from natural
2 history studies as well as clinical trials, to that
3 effect.

4 So I don't think that we're wise to just
5 say the only thing worth looking at as a clinical
6 endpoint is some kind of a virologic response, whether
7 it's binary or continuous, but that we ought to look
8 at the evolving natural history data that's clearly
9 already useful for prognosis and see if that data can
10 be used as a part of a clinical endpoint.

11 You would end up with an absurd situation
12 of taking a heavily pretreated population into a
13 clinical trial, deciding that they had met some
14 virologic endpoint. Maybe they were within .3 or
15 whatever or their baseline viral load but their CD4
16 counts were still rising and they had few, if any,
17 other treatment options. You would declare them a
18 failure and take them off study.

19 I think it's a legitimate scientific
20 question to study: How long does the benefit last in
21 a controlled setting, and what do you do with the
22 patients who are in that intermediate zone of having
23 met an approximate virologic endpoint but have not met
24 an immunologic or clinical endpoint?

25 ACTING CHAIRMAN GULICK: Dr. DeMasi and

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1 then Dr. Pettinelli.

2 DR. DeMASI: Just a couple of comments
3 about the composite endpoint and then potentially
4 multiple metrics of a viral load response or CD4
5 clinical endpoints to use as efficacy endpoints in
6 clinical trials.

7 I think that there is some data if the
8 surrogate markers work looking at the correlation
9 between CD4 and RNA in clinical disease progression.
10 Most of those analyses did show the independent
11 prognostic value of CD4 and RNA in terms of predicting
12 clinical disease progression or death.

13 And some of the analysis did rank the
14 endpoints in terms of decrease or increase in RNA and
15 a decrease or increase in CD4 count. In looking at
16 the discordant responses, the intermediate response,
17 obviously patients doing better in viral load and
18 better in CD4 are the best responses. And the
19 patients doing worse relative to baseline would be the
20 last category. So you could have a ranked endpoint
21 including both CD4 and RNA in that fashion.

22 The second point regarding the multiple
23 metrics of viral load response and/or CD4 count or
24 clinical endpoints is such that the protocol study
25 could be designed to look at as a primary analysis

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1 differences in any one of the endpoints and an
2 additional secondary step-down procedure could be
3 looked to see what endpoint is statistically, not only
4 statistically, significant but clinically meaningful.

5 ACTING CHAIRMAN GULICK: Dr. Pettinelli
6 and then Dr. Cunningham.

7 DR. PETTINELLI: My only comment is maybe
8 even in this case of having an endpoint, we might want
9 to consider the population we are dealing with.

10 For example, for patients who have an
11 option from whom we would expect a somewhat boost
12 virologic response, then we might go back and look in
13 percent of patients undetectable and so on. For more
14 advanced patients in this situation, it may be
15 different. So somehow I think we need to tailor.

16 Also I think we should not forget
17 toxicity. If that uses a primary endpoint or
18 secondary endpoint, I think it's very important to be
19 able to discern what is the toxicity vis-a-vis the
20 activity of the compounds.

21 ACTING CHAIRMAN GULICK: Dr. Cunningham?

22 DR. CUNNINGHAM: I've been remiss in my
23 job to continually remind everybody about children,
24 but that's because, really, I thought you guys were
25 talking about pediatric trials all day.

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1 ACTING CHAIRMAN GULICK: We were.

2 DR. CUNNINGHAM: In actual fact, every
3 single discussion that's occurred today, including the
4 CD4 and RNA discussion and endpoint discussion and all
5 of the discussions this morning about trial design are
6 really the same issues for pediatric patients. In,
7 really, almost all of the trial design options that
8 were discussed this morning, there are sufficient
9 pediatric patients to entertain.

10 I think regarding the issue of the CD4 and
11 the RNA endpoints, in pediatrics, we would still
12 primarily like to see an antiviral effect and would
13 expect to see that as a primary endpoint in all
14 treatment trials but also agree that you have to look
15 at CD4s as well because there are patients with the
16 discordant response.

17 It's funny. I haven't felt compelled to
18 say, "You're leaving out children" because, in actual
19 fact, there is not a single discussion that has
20 occurred today where children do not have the same
21 issues with access to drugs and access to trials and
22 needing that information.

23 Actually, every time you guys put up a
24 study, I was just picturing 5-year-olds. You guys
25 were just picturing 30-year-olds.

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1 ACTING CHAIRMAN GULICK: Ms. Delph and
2 then Dr. Deeks.

3 DR. DELPH: Dr. Delph.

4 ACTING CHAIRMAN GULICK: Dr. Delph.
5 Excuse me.

6 DR. DELPH: It doesn't matter.

7 I think that it's important to look at the
8 metabolic toxicity endpoints, including the
9 cardiovascular metabolic CNS GI and toxicities. But
10 I would also like to make a point which doesn't quite
11 fit into the endpoints, strictly speaking, but I think
12 it probably best fits here. And that is the
13 importance of monitoring adherence and in designing
14 these trials to ensure that there are interventions to
15 improve adherence.

16 Many of these patients are at this stage
17 because of difficulties with adherence and staying on
18 very complex regimens. And I think that it is
19 particularly important as one embarks on trials in
20 heavily treatment-experienced patients who have very
21 limited options to ensure that good interventions are
22 done at the beginning and during the trial to ensure
23 that adherence is optimal.

24 ACTING CHAIRMAN GULICK: Thanks.

25 Dr. Deeks?

1 DR. DEEKS: I just want to back up a
2 little bit. I think that the endpoint really is going
3 to be determined by the goal of therapy. I think the
4 goal of therapy sort of varies depending again on the
5 patient populations.

6 Implicit in the entire discussion about
7 the factorial design of wanting to combine two and
8 three drugs at once is that, at least in that study,
9 the specific therapy is complete viral suppression.
10 That's why we're obsessed about combining all of these
11 new drugs together.

12 So I think if that relatively early
13 patient population with some options in which we're
14 trying to combine two or three new agents, the reason
15 for doing all of that is complete suppression and the
16 endpoints should be the proportion undetectable.

17 I do believe, however, that we are moving
18 toward a different goal of therapy, particularly with
19 the more heavily appreciated population, in which that
20 really isn't an option.

21 If that no longer is an option, then it's
22 really delta viral load. And if it's delta viral
23 load, we don't have to worry so much about combining
24 drugs anymore. And that's part of why I was in
25 support of the add-on study design, at least for some

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1 patients.

2 I think in that situation, -- Mike was
3 talking about this earlier -- there is a very strong
4 relationship between delta viral load and delta CD4
5 and that maintenance of at least a half log drop in
6 viral load appears to be associated with the ability
7 to maintain a CD4 count above a pre-therapy baseline.
8 And I do believe that that is a very reasonable goal
9 of therapy and, therefore, would be a very reasonable
10 endpoint in that specific setting.

11 I'm just going to take it to the next
12 step. If that is the goal of therapy and we're
13 basically going for partial suppression, then I think
14 what we need to know and what needs to be studied in
15 clinical trials is not the baseline predictors of
16 success but the treatment predictors of failure.

17 Therein lies the need to study the
18 evolution of resistance and relate the emergence of
19 mutations to loss of antiviral effect. And also
20 involved in those types of studies would be a careful
21 evaluation between the relationship between drug
22 resistance and virus fitness and their impact on viral
23 load and CD4 counts.

24 ACTING CHAIRMAN GULICK: Dr. Eron?

25 DR. ERON: I think one service the ACTG

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1 could do is to take the data from our three or four
2 advanced studies, like 398, 359, 372B, and see what is
3 the relationship in an individual between change in
4 RNA and change in CD4 and see if what Steve says
5 actually does hold up because my sense, anyway, was
6 that in the nucleoside-only era, they were kind of
7 mirror images of each other.

8 The RNA would go down. The CD4 would go
9 up. And then the RNA would come up and the CD4 go
10 down. You didn't quite see as much of this
11 discordance. I don't know if that is true or false,
12 but one could imagine if that were the case and with
13 our triple combination or other regimens, where there
14 actually seems to be more of a CD4 effect, that,
15 actually, you get more clinical benefit from a smaller
16 change in viral load potentially. So it would be nice
17 to know what that relationship is, and we certainly
18 have a ton of data to figure that out.

19 ACTING CHAIRMAN GULICK: Doctor?

20 DR. DEEKS: Mike talked about this. One
21 concern, though, is in the study that you referred to,
22 we don't have a good feeling of those patients' sort
23 of off-therapy set point because I think that's the
24 delta viral load that's important.

25 There's a chain in viral load from

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1 wherever that virus goes in the absence of therapy.
2 And with 359 and so forth, we might not actually have
3 that since we have data going back to before 320.

4 But that is the analysis that needs to
5 happen, the relationship between the degree of viral
6 suppression relative to what the viral load was long
7 before therapy and how that impacts on CD4 changes.
8 I don't think that type of analysis --

9 DR. ERON: Certainly 320 would be the
10 place to get that. You wouldn't quite get it because
11 many of the 320 patients were AZT-experienced. But it
12 would be pretty close.

13 ACTING CHAIRMAN GULICK: Dr. Falloon?

14 DR. FALLOON: I would argue against the
15 composite endpoint in part because I don't think we
16 know how to define it. If you go back to the original
17 trials and you look at the CD4 elevations in AZT load
18 or ddI, -- I mean, my memory is at 11 cells -- we're
19 talking about something given the variance of the
20 measure.

21 To power those studies, I think we would
22 have to have larger numbers. We don't know how to do
23 it, and it's also different across the spectrum of CD4
24 counts, a total number.

25 If your CD4 count is 400, it is completely

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1 different in change than if it's 10, where you have to
2 look at percent. So all of those things would have to
3 be taken into account.

4 Now, perhaps the statisticians could think
5 about it. None of us is easily thinking of a
6 composite measure that works. And that makes me think
7 we should simply go back to viral load.

8 ACTING CHAIRMAN GULICK: Okay. Let me try
9 to summarize here, then. In considering what the best
10 endpoints are, we once again touched on who the
11 population is and once again recognized the
12 heterogeneity. Once again, the set point and the
13 possible effects of washout of therapy and what the
14 pre-treatment therapy was are all important factors.

15 I guess our overall goal in terms of
16 endpoints is to pick agents which promote clinical,
17 positive clinical, effects, but the feeling was that
18 we go back to the old standbys. These are
19 antiretroviral agents. And viral load levels become
20 probably the most important, although not the
21 exclusively important, endpoint.

22 Whether our goal is complete virologic
23 suppression for some patients, looking at the percent
24 below detection, or partial virologic suppression,
25 looking at a change in viral load -- and I guess the

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1 consensus was that a .4 to .5 log change over 8 weeks
2 is about the minimum that people felt would be
3 correlated with a positive clinical outcome.

4 Other things that people mentioned: an
5 AUCMB approach to viral load change; time to failure;
6 and then not forgetting other properties, virologic
7 properties, like resistance and fitness.

8 The relationship between the viral load
9 and the CD4 is very intriguing to people, probably an
10 independent predictive relationship, but what's the
11 interaction of those two endpoints? Not well-defined
12 right now.

13 People pointed out that CD4 certainly has
14 predictive value for sure and intermediate risk of
15 clinical events and the well-known discordance
16 response data important to keep in mind.

17 Other important endpoints that people
18 mentioned, toxicity, adherence. It wasn't voiced but
19 quality of life endpoint is all important to think
20 about in this population.

21 There was some disagreement about the
22 usefulness or the feasibility of using a composite
23 endpoint of CD4 and viral load. How do you define
24 that? People thought certainly looking at both was
25 appropriate, whether you could really combine them,

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1 some differences of opinion.

2 Using sequential endpoints was another
3 novel concept that came up. There was some voiced
4 approval for trying to use continuous, rather than
5 binary, outcome variables.

6 Other interesting points that people made,
7 most of our discussion has been about antiretrovirals,
8 but certainly other types of agents may be used and
9 other endpoints might be appropriate; for instance,
10 immune-based therapies. Lastly, there was an interest
11 in identifying predictors of failure, either at
12 baseline or while people are on treatment.

13 In our last minutes, let's consider the
14 last question: Please discuss the role of
15 shorter-term trials; that is, 16 weeks, in assessing
16 safety and efficacy. Importantly, please consider the
17 needs to establish longer-term safety. So we have
18 been focusing on activity endpoints. And now we're
19 shifting to time periods and safety endpoints.

20 Dr. Pettinelli?

21 DR. PETTINELLI: It was mentioned earlier
22 today that we should study drug in the condition in
23 which it will be used in the clinic. Hopefully that
24 use will be longer than 16 or 24 weeks. Why for
25 access purposes, I understand that for accelerated

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1 approval, we might need to look at 24 weeks data.

2 I think it's really a requirement, very
3 important, that we continue to follow up with these
4 patients over time, only up to 48 weeks. By those
5 same terms, if those patients have other options, how
6 this particular regimen is going to influence the
7 future options.

8 So long-term follow-up, both in terms of
9 efficacy and safety, for me is a very, very important
10 part of the development of the new compound.

11 ACTING CHAIRMAN GULICK: Dr. Fletcher?

12 DR. FLETCHER: In terms of antiviral
13 effect, I think a short period has already been talked
14 about, 8 weeks to 16 weeks, certainly should be able
15 to tell us whether a compound has the ability to
16 reduce viral load.

17 As Carla pointed out, we still may want to
18 know and probably need to know longer-term as well,
19 but if the primary question is "Is this drug behaving
20 as an antiretroviral?" then a short-term assessment
21 can answer that question.

22 I think in terms of safety, the other
23 issue that we have to look at in evaluating how far we
24 have to go comes back to the issue of exposure if
25 we're now using the drug in a manner in the heavily

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1 pretreated patient in which we don't use it in the
2 naive; so, for example, in a boosted regimen, levels
3 10-20-fold higher than what is done, for example, in
4 naive.

5 You have I think an obligation to study
6 that drug for probably a longer period of time for
7 safety purposes than you might have studied it for use
8 in naive patients simply because the drug exposure is
9 so much different.

10 The same issue could hold with the
11 combinations. If you're now using the drug with other
12 agents that you would otherwise never use it with,
13 again, this heavily pretreated group of patients,
14 then, again, you may have a different length, a longer
15 length, of time to assess safety than you would in a
16 naive population.

17 ACTING CHAIRMAN GULICK: Dr. Mellors?

18 DR. MELLORS: You know, I think this is an
19 incredibly difficult issue. And it's a risk/benefit
20 assessment. If the situation is high-risk for disease
21 progression, then you're going to be satisfied with a
22 lot shorter-term safety data and make your decision
23 largely based on virologic and immunologic effect.

24 To get longer-term good safety data, you
25 have to maintain a comparison. The longer you

1 maintain the comparison, the longer you delay the
2 completion of the trial and approval. So I think that
3 it is a very difficult tension between safety and
4 efficacy.

5 I see it as when we're dealing with an
6 advanced population with limited treatment options, if
7 we're dealing with those who are near clinical events
8 and we're trying to have an impact on that group, we
9 may sacrifice the duration of safety observations to
10 allow access to the drug. If we're dealing with a
11 group that is less at risk for clinical events, then
12 we can maintain the comparisons longer and get better
13 safety.

14 Again, it depends on what the drug is
15 being developed for. If it is being developed for
16 heavily treatment-experienced patients, for that
17 group, I'm willing to compromise the duration of
18 safety assessment and accelerate approval, recognizing
19 that when I do that, I take a risk at not fully
20 defining the long-term safety trial. But I'm more
21 willing to do that in that situation.

22 ACTING CHAIRMAN GULICK: Dr. Fletcher, a
23 follow-up; and then Ms. Dee.

24 DR. FLETCHER: I don't disagree, John, and
25 I think we can go back to what the agency has talked

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1 about in terms of accelerated approval and the tools
2 that they have to grant a drug an early accelerated
3 approval but require additional studies.

4 So certainly if you have an agent that
5 looks fantastic for use in the heavily pretreated
6 patients and good evidence of an antiviral effect in
7 safety at 16, 20, or 24 weeks, an accelerated approval
8 could be very appropriate, but it could be a wonderful
9 setting in for requirements for longer-term
10 evaluations as well.

11 So I don't disagree with you. I in my
12 comments didn't mean to imply at all it had to all
13 come together, but I think it probably all does need
14 to be done.

15 ACTING CHAIRMAN GULICK: Ms. Dee?

16 MS. DEE: Yes, thanks. My concern here is
17 that we have a problem now in that we have 24-week and
18 48-week data as far as long-term safety is concerned.
19 If we approve drugs now at 16 weeks, then they're
20 off-label uses of these drugs. So you will have other
21 people besides the deep salvage patients using these
22 drugs.

23 You know, if I felt like or if I were
24 sure, I guess, that some of these other studies would
25 get done or that we would get long-term safety data,

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1 eventually somehow I think I would feel much more
2 comfortable in saying, "Well, maybe 16 weeks is okay,
3 even if patients that are not deep salvage patients
4 would try this."

5 We're talking about this tension all day
6 long. I think we have to be realistic that once a
7 drug is approved, it's approved. How do we make sure
8 this other stuff gets done?

9 ACTING CHAIRMAN GULICK: Dr. Delph?

10 DR. DELPH: I want to reiterate what Lynda
11 was saying. She did make some of the points that I
12 wanted to make, but, in addition, I think we can do
13 interim analyses for efficacy at 16 weeks. But I
14 don't think we should be looking at approving drugs at
15 16-week safety data.

16 If the objective is to get patients who
17 have few options available to them to be able to get
18 access to these drugs as early as possible, then the
19 answer is to open up expanded access earlier. These
20 are patients who are willing to take a risk but who
21 should not be required to enter trials simply to get
22 drug.

23 I share in this concern very much about
24 approving drugs before getting at least 24 weeks data
25 for accelerated approval and 48 for standard approval

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1 because of the possibility of off-label use.

2 The difficulty is that once the cat is out
3 of the bag, the drug can be used in a variety of ways
4 for which it is not intended or there is not adequate
5 data. And, secondly, the record on being able to get
6 adequate safety data once approval has occurred is
7 dismal.

8 ACTING CHAIRMAN GULICK: Dr. Saag?

9 DR. SAAG: I think those are points that
10 are well-made. My struggle is that I'm not sure that
11 24 weeks is that much better than 16 or 48 is much
12 better than 24.

13 I mean, most of the problems that we have
14 encountered in the longer-term, a 48-week study
15 wouldn't have predicted. It was really two and three
16 years into it that we started noticing fat
17 redistribution and diabetes and things. So I think
18 we're sort of beating ourselves up in a way that maybe
19 isn't going to solve the problem. That's on one side.

20 On the other side, I mean, again, I don't
21 know how different my population is, but I'm looking
22 every day at people who have run out of options. If
23 there is a new drug in a new class or a new drug in an
24 old class that has new, unique activity, expanded
25 access is okay, but there's a cost that goes with that

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1 that's hidden.

2 That's a hidden cost to the site, where we
3 processed 100, for efavirenz, we processed 100,
4 applications and had to renew them monthly. That took
5 an enormous amount of effort. So there is cost on the
6 other end, too, to the site. We don't get reimbursed
7 for that. We have to hire new people to do that. And
8 it's a loss to us. We do it for the sake of helping
9 the patients.

10 So I think what we're saying here is that
11 we would like to provide the access. The question is,
12 the concern is, that if we provide it, quote, "too
13 early," that we don't hold industry accountable to an
14 obligation. So let's get it out early and find
15 another way of holding accountability for getting the
16 data. That's what I think we should do.

17 ACTING CHAIRMAN GULICK: Dr. DeMasi and
18 then Dr. Fletcher.

19 DR. DeMASI: I just wanted to bring up a
20 couple of points with respect to this and based on the
21 comments made this morning about the complexity of the
22 populations we're dealing with, the drugs involved,
23 the difficulty in demonstrating safety and activity
24 and efficacy in this population, that there needs to
25 be I think a flexibility in terms of the packages and

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1 approaches to drug development in this setting and
2 that it's not a one size fits all, it's not a 16 and
3 a 48 or a 24 and a 48-week type of submission.

4 I would just offer for discussion the
5 possibility of a particular week, 16, efficacy and
6 safety type of submission for accelerated approval and
7 then following that up with some other interim time
8 point before week 48 in terms of more traditional
9 approval to generate additional safety data.

10 ACTING CHAIRMAN GULICK: I'm sorry. Dr.
11 Delph, did you have a direct response to Dr. Saag?
12 Okay.

13 DR. DELPH: I really don't like to respond
14 to people in their absence, but I'll do it. I think
15 that certainly I take his point about the fact that
16 the toxicities that we noticed, the major toxicities,
17 lipodystric enzyme, came on much later than 24-48
18 weeks. So we noticed them much later. But moving
19 from 24 to 16 weeks is decreasing that time by a
20 third.

21 I understand the cost that occurs with
22 trial sites in terms of having to process all of these
23 papers. We have been trying to work with companies to
24 move that from every month to every three months and
25 so on. But I think that that kind of financial and

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1 administrative cost is far less of a price to pay than
2 that of patient safety. That's one.

3 Two, I think that we need to do it the
4 other way around, that companies need to demonstrate
5 that they are prepared to provide that long-term
6 safety data and that data that extends beyond 48 weeks
7 before we'll turn around and say, "Fine. We'll
8 approve drugs at 16 weeks."

9 I don't think we should be saying "Let's
10 approve drugs at 16 weeks" in the hope that they will
11 be providing that data long-term. I think they need
12 to demonstrate that that is something that they are
13 committed to doing.

14 ACTING CHAIRMAN GULICK: Dr. Fletcher and
15 then Mr. Levin.

16 DR. FLETCHER: Mike Saag really ended up
17 on the expanded access where I was, that you have that
18 balance you have to struggle with between a drug that
19 looks very promising that you want to get out to
20 individual that can't access clinical trials.

21 But at the same side, an expanded access
22 is not a substitute for an unambiguous answer in terms
23 of whether this drug has antiviral activity and is
24 safe. So it is that balance that I think has to be
25 kept in mind.

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1 I agree with the comment about obtaining
2 clear commitments for longer-term safety evaluations
3 of these compounds when they are approved on a more
4 accelerated schedule.

5 ACTING CHAIRMAN GULICK: Mr. Levin?

6 MR. LEVIN: I agree with Yvette and Lynda.
7 I am all for 16 weeks. That's okay. The FDA and the
8 community and the researchers are sitting here at the
9 table today. Where is the industry?

10 I need a commitment from the industry that
11 they will do the follow-up. That's why I mentioned I
12 think the important -- how I feel it's important to
13 set up maybe a cross-salvage or experienced person
14 studied across all studies, some sort of a database to
15 collect information and to continue collecting
16 information across all of these studies over a period
17 of time.

18 I don't think one year is enough. It
19 takes two years for lipodystrophy. What about again,
20 for the third time, hepatotoxicity? Why can't we make
21 it? I don't know what the law is, but why can't we
22 speak to the industry to make a commitment on this,
23 and it's a deal?

24 ACTING CHAIRMAN GULICK: Dr. DeMasi?

25 DR. DeMASI: Yes. Just with respect to

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1 some of the time points for the particular analyses,
2 16, 32, 48 weeks, I think because of the staggering
3 enrollment of the studies that you do have additional
4 data beyond those time points that is included or
5 should be included in the analyses that would, for
6 example, support a week 16 submission or submission
7 based on week 16 data or week 24, whatever the time
8 point is.

9 Because of the staggering enrollment, we
10 do have patients that are out to 48 weeks, that are
11 out to 72 weeks, 2 years. And that data I agree
12 should be presented as part of the package and data
13 continue to be collected.

14 ACTING CHAIRMAN GULICK: Dr. Schapiro?

15 DR. SCHAPIRO: I would agree with what
16 Mike and Corny were saying regarding you really have
17 to be able to get the drug out quickly. We're saying
18 that.

19 We really can't sort of tell the agency,
20 on the one hand, these patients need these drugs
21 desperately and then say "But we require two years of
22 safety." It doesn't work both ways.

23 I also think that technically expanded
24 access is good, but to make that the general policy of
25 how we're going to approve all of these agents, I

1 don't think it will work when we try to implement it.
2 Although it's a good idea, it will be very difficult
3 to do that large-scale.

4 I think what Jules was saying is true, but
5 I think we can probably help industry with some
6 guidance how that has to be done. The concepts
7 earlier today were brought up of a database. I think
8 they're realistic.

9 I think John made a good point that you
10 can't just follow patients. There has to be a
11 comparator. I think we can probably -- it's probably
12 beyond the scope of this meeting, but we could come up
13 with some ideas how that could be done.

14 Patients who are on these drugs can be
15 entered and followed in some way and a comparator
16 group can be found of comparable patients who are not
17 getting the drug.

18 There can be a committee, and this could
19 be the financial burden of the sponsor. But I think
20 as far as running this, it could be done also by the
21 community, academia, under the guidance of the agency.
22 And then we wouldn't do a final 48-week. This would
23 be an ongoing process for drugs that are approved.

24 We accept that due to this patient
25 population, they're going to get out early. But we

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1 would set up a mechanism by which these patients
2 receiving the drug are followed for toxicity. We
3 probably couldn't do it at every time point, but we
4 have large databases that are setting up.

5 The idea is we have databases for
6 resistance. We have some very large databases which
7 have given us wonderful information. We can do
8 something similar here with a comparator group and to
9 continue to look. I think, as Mike said earlier,
10 there's nothing magical about week 48. We would
11 probably have to look beyond that as well.

12 ACTING CHAIRMAN GULICK: Dr. Jolson?

13 DR. JOLSON: I would concur with many of
14 the previous speakers. I think we're becoming
15 increasingly aware of the importance of longer-term
16 data. We have been trying to reflect that data and
17 package labeling as an incentive to sponsors to
18 continue to collect data beyond the one-year mark or
19 a year and a half-mark and trying to include as much
20 of that information as possible because we think it's
21 extremely important.

22 I think we would also agree that there
23 need to be more collective efforts in terms of how
24 we're going to approach that and collect the data and
25 follow patients long term. It's not an easy thing to

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1 do.

2 In terms of how much safety data would we
3 need to approve a new drug, I would have to share some
4 of the sentiments that the community raised that I
5 would be concerned about not having at least some
6 cohort of patient out beyond 16 weeks in terms of
7 predicting the safety.

8 You know, when you work at FDA, the
9 pendulum in public sentiment swings back and forth in
10 terms of how quickly drugs should be approved. When
11 we have in our mind a drug that is very, very
12 effective, it's impossible not to say, "Well, let's
13 get it out as quickly as possible."

14 But you have recently lived through as an
15 agency experiences where drugs are marketed and then
16 there is some sort of adverse event that happens, it
17 is very hard to justify it in hindsight. It is
18 particularly harder to justify it if the databases
19 isn't as robust as would have been necessary.

20 Data. There is always some risk there,
21 but I think it would be enormously difficult to
22 conceive of a situation where we wouldn't want some
23 data beyond 16 weeks. It doesn't have to be in the
24 same group of patients as in the Phase III studies.
25 And my message to industry would be to strongly

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1 encourage following your patients from earlier studies
2 as long as possible.

3 If you look at, again, the Kaletra label,
4 you will see longer-term data reflected from studies
5 that were started earlier in development. It was
6 enormously useful. And it is a time saver. It's the
7 sort of data that would enable us to make decisions
8 based on shorter-term efficacy data.

9 ACTING CHAIRMAN GULICK: Ms. Dee?

10 MS. DEE: You know, the expanded access
11 programs are to give people access to the drugs, not
12 to approve the drugs. I'm not sure why we would mix
13 that up.

14 You have the expanded access program to
15 give people access to it while you're studying it to
16 find out if it really does do what you hope it does
17 and to see the toxicities, which you could see with
18 controlled trials and the other, and the expanded
19 access program.

20 But I'm from Missouri. It's funny.
21 Yvette just commented that the patients'
22 representatives are saying that we want more
23 restrictions, and the doctors are saying, "Let's get
24 it out there."

25 We want to first do no harm. I mean,

1 let's see from industry how they're going to address
2 these situations before we open the floodgates again
3 to say, "Okay. Let's approve a drug at 16 weeks and
4 hope that something will happen past 48 weeks, when
5 there's no statutory authority to make that happen."

6 So I don't know if anybody from industry
7 wants to comment on that about how we might be able to
8 -- what their plans are for that in the future, but us
9 saying that, "Yeah, they should do that" is just not
10 enough for me or them saying they're just going to do
11 that without some firm plans, demonstration, or some
12 sort of demonstrative evidence.

13 ACTING CHAIRMAN GULICK: Dr. DeMasi?

14 DR. DeMASI: Yes. I think just to
15 clarify, in the discussion, the mention of the week 16
16 analysis, I believe what we're talking about is: What
17 is the duration of a particular interim analysis of an
18 ongoing study that could be used as a basis for an
19 accelerated approval filing, particularly for efficacy
20 data?

21 And that's not to say that no other data
22 would be collected beyond 16 weeks, but that defines
23 I think what is sufficient for a submission and that
24 we do support the collection of data, as mentioned
25 before, in that study, additional follow-up data to a

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1 later time point as well as additional follow-up, for
2 example, of earlier Phase II studies, in which you do
3 have patients out to week 48, 72, and 96, as was
4 mentioned in the Kaletra label.

5 ACTING CHAIRMAN GULICK: Okay. I think I
6 would like to stop us there. Just to summarize, I
7 think we began consideration of safety endpoints much
8 the way we began the consideration of all of the other
9 questions. That was to consider the specific patient
10 population.

11 As was pointed out, higher doses may be
12 used in this population or PK enhancement. Therefore,
13 exposures to drugs may be higher in this population
14 than naive patients. We also pointed out that
15 concomitant medications are likely to be many more
16 used in this patient population.

17 It was pointed out that we might be much
18 more tolerable of risk in this population and accept
19 greater toxicity and/or shorter follow-up data.
20 However, there was a general feeling that a
21 significant amount of safety information should be in
22 place.

23 There was some debate about the actual
24 number of weeks, but it was really stressed that we
25 needed a commitment from the sponsors to have

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1 longer-term follow-up of safety endpoints.

2 There were some novel suggestions once
3 again, that long-term cohort studies or database-type
4 data may be helpful in looking at longer terms.

5 Then, once again, we really identified the
6 conflict of access to agents that may show viral
7 activity versus safety and how do you resolve that
8 conflict, not something we did today.

9 Lastly, importantly, pointed out by the
10 agency that safety data can come from other places.
11 Other studies of the same drugs can often provide
12 safety data that can help support this, too.

13 With that, I would like to thank the
14 presenters for today. I would like to thank the
15 Committee themselves for an extremely lively
16 conversation, thank members of the agency and members
17 of the audience. Thanks very much. We will close.

18 (Whereupon, the foregoing matter was
19 concluded at 5:30 p.m.)

20

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CERTIFICATE

This is to certify that the foregoing transcript in the
matter of:

Meeting of the Antiviral Drugs
Advisory Committee

Before: DHHS/PHS/FDA/CDER

Date: January 11, 2001

Place: Bethesda, MD

represents the full and complete proceedings of the
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