

1 this drug. As has been emphasized, it is a different class  
2 of drugs. It is once daily and, in many ways, it is  
3 convenient to take. So, I think the company should be  
4 applauded for developing this. But I would agree with most  
5 of the previous comments that it would certainly be  
6 desirable to have a more robust database that would indicate  
7 that the drug is useful or is active in the patient  
8 populations being studied.

9 I think from the Phase I and Phase II studies and  
10 from 408, there clearly is activity, although it isn't clear  
11 in my mind that this meets the definition of having two  
12 studies with adequate data and adequate follow-up to provide  
13 us enough guidance as to how to use it.

14 So, I don't think that the data about 120 mg,  
15 although promising, meet my definition for proving activity  
16 yet, and considering the comments that have been made about  
17 the toxicity, I think there is a lot to be learned there.

18 So, clearly if we need a better database on 120  
19 mg, I think indicating that 60 mg is effective is premature  
20 based on what we have seen so far.

21 DR. HAMMER: Thank you. Dr. Hamilton?

22 DR. HAMILTON: Perhaps an initial editorial  
23 comment will explain my position, which is that efficacy has  
24 not been satisfactorily established for the 120 mg dose, nor  
25 has the 60 mg dose been confirmed as comparable.

1           The editorial comment includes the following: I  
2 am always incredibly impressed with personal testimonies and  
3 impassioned appeals for the licensure of drugs. I have no  
4 doubt that in those instances those are heartfelt beliefs in  
5 every case, and I have also no doubt that there was a lot of  
6 substance to the comments. However, we need to revisit what  
7 I think the charge of the committee is, which is to  
8 critically assess, by means of a systematic evaluation of  
9 systematically and scientifically conducted clinical trials.  
10 I think that is so important because I think what we are  
11 being asked to do is, on the basis of limited and arguably  
12 unrepresentative data, to decide whether drugs have some  
13 effects and in a very limited and confined arena.

14           Though everyone does not necessarily share this  
15 view, it is my opinion that we are evolving more and more  
16 into the need to address not the short-term implications of  
17 drug therapy but the longer-term consequences of drug  
18 therapy in a disease that is now chronic. Fortunately, we  
19 have 13 or 14 drugs that have been approved. Fortunately,  
20 there has been a dramatic decline in mortality and  
21 morbidity. But now it is a different scenario and we are  
22 talking about people taking drugs for year and year and  
23 years, and that is great, but I think we need to adopt new  
24 strategies to **assess** the value of those drugs. And, that  
25 may be bad news to industry but I think that is where we are

1 going, and short-term clinical trials I just don't think are  
2 stepping up to the plate there.

3           So, in summary then, as I said at the outset,  
4 though there is some evidence for modest antiretroviral  
5 effect in a single trial, 408, there is not a confirmatory  
6 trial at that dose. By that definition alone, it would not,  
7 in my opinion, meet the criteria for efficacy.

8           The comparison with 60 mg, it seems to me, is  
9 confounded by a variety of circumstances, including the  
10 complexity of the studies, the possibility of drug  
11 interactions, the short term of the trial, and the large  
12 number of missing data making pooling of the data suspect.  
13 For those reasons, I would not accept efficacy of 120 mg,  
14 nor would accept 60 mg as comparable.

15           DR. HAMMER: Thank you. Dr. Yogev?

16           DR. YOGEV: Early my career was as schizophrenic  
17 as I am with this specific drug. Listening to the personal  
18 testimony, one cannot avoid compiling how many drugs those  
19 patients were taking and you find out it was six, eight, ten  
20 drugs, and in the studies which were presented to us there  
21 were not that many drugs. So, I think that the 120 mg does  
22 have some marginal effect -- if one can block the other  
23 schizophrenic portion of me -- when you are out of  
24 desperation trying to use this, it is easier to take a drug  
25 that may has some marginal effect, I think that would be a

1 place where I would say, yes, the 120 marginal effect might  
2 be there. But I was not at all convinced that there is any  
3 comparability with the 60 mg.

4           So, I would say that under the public request, and  
5 I think when you do a critical review you have to be also  
6 somewhat human and not just look to science, this margin  
7 would be enough for me in a very rare patient. And, there  
8 were 9000-plus going into it, so there were some physicians  
9 along the line looking for something that we don't have  
10 today. So, if someone can limit it somehow that if you take  
11 six drugs or above you can take this marginal, and it is  
12 your choice with the addition with all the toxicity that is  
13 there, I might say that this marginal might be sufficient  
14 for patients experienced, which many of my colleagues and I  
15 interpret as taking AZT for more than six weeks -- that is  
16 dangerous and I don't think the data are there. So, 120  
17 very marginal, adding toxicity, and the need in a small  
18 number of patients probably has a place for this drug, but I  
19 am not sure that 60 at all is the right answer.

20           DR. HAMMER: Thank you. Dr. Mathews?

21           DR. MATHEWS: Before answering the first question,  
22 I think implicit in any discussion of accelerated approval  
23 is, is there a population in need of an agent with this  
24 drug's characteristics. I think very definitely there is a  
25 need. I think that the volume of the expanded access

1 program clearly indicates that physicians and patients are  
2 scrambling like wild to find agents with some activity that  
3 can be components of salvage regimens for people with very  
4 limited treatment options.

5           So, having said that, I want to say that I don't  
6 think that the CPCRA study can be properly evaluated for  
7 efficacy, and a number of comments have been made as to its  
8 negative effect, but I don't think that is a fair appraisal  
9 of the results and the agency itself has not had access to  
10 the full data set, from what we have been told. The ACTG  
11 359 study, I think, is quite problematic in terms of the  
12 unanticipated results, the possible drug interactions that  
13 weren't anticipated in the company's previous drug  
14 interaction studies. So, I think that is worrisome but,  
15 once again, that data set has not been fully evaluated.

16           Based on the Phase I/II studies and the 408 study,  
17 there is little doubt in my mind that the drug has modest  
18 activity, of the same order of magnitude of agents that were  
19 previously approved in related drug classes. So, I would  
20 say, yes, there is activity and it is of a modest nature,  
21 which other people have said.

22           Now, with regard to the equivalence issue with the  
23 60 mg dose, you know, I looked with some attention at both  
24 the FDA's analysis and the sponsor's analysis of the  
25 equivalence trial, and I must say understanding the

1 statistical complexities of equivalence designs is not easy.  
2 However, the point estimates of the drug effect were clearly  
3 equivalent or better for the 60 mg dose, and the issue of  
4 the statistical interaction between dose and concomitant  
5 regimen I think is debatable, and I couldn't come to a  
6 conclusion either way from either the sponsor's or the  
7 agency's discussion.

8           So, I am reasonably confident that the 60 mg dose  
9 is equivalent to the 120 mg dose. On the other hand, the  
10 sponsor's proposed dosing guidelines and toxicity management  
11 program uses a 30 mg dose, for which I could see no data at  
12 all to support efficacy, and I would have major problems  
13 with that as being part of a recommended management strategy  
14 if the drug is licensed.

15           Now, with regard to the toxicity -- oh, we are  
16 just talking about question one right now?

17           DR. HAMMER: Right now. We will come back to  
18 questions two and three but let's stick with question one.

19           DR. MATHEWS: Okay. I think both limited efficacy  
20 and equivalence have been demonstrated.

21           DR. HAMMER: Thank you. Dr. Stanley?

22           DR. STANLEY: Thank you. Given the advantages of  
23 this drug, I wish that I could say that it is ready to be  
24 approved but, unfortunately, I think the answer to question  
25 one is no also.

1           Basically, they are asking us to make a decision  
2 on efficacy based on one study, 408, and the effect in that  
3 study **was** minimal. I think it was there so I am ready to be  
4 convinced, but I need to see at least another study, as is  
5 required by the FDA for accelerated approval anyway. We  
6 don't have two studies on true advanced patients that need  
7 salvage therapy. Study 417 has patients that are PI naive  
8 and 411 had completely naive patients. So, I think the  
9 company needs to decide, as I think Roger said, how they  
10 want to use this drug and then study those patients and  
11 provide us with some good clinical data that will support  
12 the efficacy of this drug in the population that they want  
13 to target it at.

14           So, additional data that would be necessary to  
15 characterize the efficacy of the 60 mg dose, as others have  
16 said, I think we need a placebo-controlled trial using the  
17 60 mg and the 30 mg dose, I think 417 is seriously flawed  
18 by not having an arm where there was no adefovir used.

19           DR. HAMMER: Thank you. Dr. Bertino?

20           DR. BERTINO: Thank you. First, I would like to  
21 thank Dr. Hamilton for his very thoughtful comment. He said  
22 a lot of the things that were going through my mind.

23           I think that in terms of my response to the  
24 question, I don't believe there is data to suggest that the  
25 120 mg dose is effective. I think that one of the things

1 that many of us probably were surprised about when looking  
2 at 417 was, as Dr. Stanley said -- where was the placebo  
3 arm?

4 So, I would suggest that if the 60 mg dose should  
5 be studied again, we probably need a placebo arm, so 120, 60  
6 and placebo perhaps, and look at patients that have received  
7 multiple therapies in the past.

8 DR. HAMMER: Thank you. Most of what has been  
9 stated I concur with. My own personal view with regard to  
10 the 120 mg efficacy dose, or at least what I would say is  
11 antiretroviral activity, that it hasn't been demonstrated --  
12 I would agree with Drs. Mathews and Wong that I believe it  
13 has if one looks at the 402 and 403 Phase I/II studies, and  
14 in the 408 study there is a consistency in the  
15 antiretroviral effect, and there are problematic issues in  
16 interpreting the 039 study. Everyone agrees that if it is  
17 there, it is modest.

18 I also think the issues of minimal, at best,  
19 modest CD4 count rise also raise issues as far as what the  
20 ultimate role and efficacy of this drug is. But my personal  
21 comment on efficacy of the 120 mg dose is that, yes, it has  
22 been demonstrated. I think there is consistency there.  
23 Otherwise, one has to try explain, in two of the studies and  
24 the larger study, the 408 study, one has to explain why  
25 there is that consistency there.



1 I would just take a step back though and say that  
2 one of the problems -- it has been a very difficult day I  
3 think for everyone here and on the committee because each  
4 study that has come up is subject to issues of  
5 interpretation, either in the design stage or the analysis  
6 stage, so trying to paint a consistent picture is difficult,  
7 and also with a drug that is of this level of antiretroviral  
8 activity it doesn't take much to undercut it because we are  
9 not dealing with a drug that has an intrinsic 0.5 log  
10 reduction.

11 That being said, I think efficacy at the 120 mg  
12 dose, to me at least, is there. On the issue of has  
13 comparability been shown between 60 mg and 120 mg, we are  
14 really left with a difficult data set to interpret. On the  
15 one hand, there is indication to me from the monotherapy 60  
16 mg trial, the 420 trial, that there is activity there, and  
17 it looks across study to be about the same in the 0.3, at  
18 the most 0.4 log range, that is a study, because of its  
19 small numbers, that the agency has said must be taken in a  
20 supportive fashion, but at least it is one of the cleanest  
21 studies. The direct comparison of 60 versus 120 in the 417  
22 study -- I have little to add to what has been stated.  
23 Basically, you either can believe it or you ask yourself  
24 where is the placebo control that helps differentiate the  
25 data because the background therapies make the comparison

1 very difficult to state.

2           So, I am left really with a conundrum. I tend to  
3 agree with Dr. Mathews that there probably is activity to  
4 the 60 mg dose. It probably does cross the threshold of  
5 just biologic and assay variability so I would tend to come  
6 down mildly in favor of the fact that it is there but can I  
7 say it has been conclusively demonstrated? The answer is no  
8 because it is based on the 417 study which, because of the  
9 design, the discontinuations, the potential of complicating  
10 drug interactions leaves us wanting additional data in that  
11 regard. So, that is my personal response to question one.

12           I would like to turn to questions two and three.  
13 I think these can be taken together since they both relate  
14 to the toxicity issues. I will read both questions and I  
15 would ask each committee member to deal with both of them,  
16 and then we will move on to the voting question, question  
17 four.

18           Question two states, had the safety profile of  
19 adefovir 60 mg been adequately characterized? In  
20 particular, please comment on the adequacy of the available  
21 data to provide labeling information regarding  
22 nephrotoxicity and its incidence and reversibility.

23           The third question, to be taken with it in tandem,  
24 please discuss the adequacy and feasibility of the sponsor's  
25 proposal for renal toxicity management.

1 I will again start on my right. Mr. Schouten?

2 MR. SCHOUTEN: I think that patients and  
3 physicians are managing this drug. Expanded access program  
4 is exposing a lot of people to this drug and its known  
5 toxicities, but I would encourage people not to be too  
6 paternalistic and **say** patients shouldn't be subjected to  
7 this risk. I am very concerned about a drug that requires  
8 someone to come in for monthly laboratory testing for both  
9 the patient and the provider. So I see it from both sides.  
10 And, I don't think you can say if you don't come in for your  
11 lab next month you don't get your drug. I think there are  
12 too many contingencies there, and I now there aren't going  
13 to be patients coming in for the drug.

14 I would like to see -- I know we had a lot of  
15 stuff to cover today -- some of the issues of rechallenging.  
16 We heard some testimony about early supplementation but I  
17 think it does have a well-defined safety profile. It is  
18 concerning but I think it is easily managed and I don't  
19 think that that would preclude licensing the drug. I mean,  
20 it is a manageable toxicity profile.

21 In terms of the sponsor's proposal for management,  
22 I would add there is an inconsistency. In one place they  
23 mention phosphate of 1.5 and in other places 2.0 for  
24 contraindication. I think what they mean is 2.0 in terms of  
25 on study, on the drug.

1           Then, the other issue is that I am concerned about  
2 recommending a dose decrease to 30 mg because of the  
3 efficacy, and would prefer to see discontinuation while that  
4 toxicity is resolving and not 30 mg. Thank you.

5           DR. HAMMER: Thank you. Dr. Kimmel?

6           DR. KIMMEL: I did not think from the data that I  
7 saw that the safety of 60 mg has been adequately  
8 characterized. I was impressed by the very small number of  
9 patients who have been followed to 48 weeks, especially  
10 since late manifestation of nephrotoxicity is when you see  
11 these issues. I think there was not enough time or patients  
12 to really evaluate the toxicity profile.

13           I was also impressed that the management plan for  
14 looking at renal toxicity -- there is very little data to  
15 say whether it is a good plan or not. We saw very little  
16 data about what the effect of monthly management is in terms  
17 of outcomes, and I felt that we just really don't have  
18 enough information to make the decision about that plan. I  
19 am a little concerned about stopping the drug and restarting  
20 the drug with very variable intervals.

21           DR. HAMMER: Thank you. Dr. Kopp?

22           DR. KOPP: I also have some very significant  
23 concerns about the adequacy of the safety data. I will say  
24 I found this a very difficult decision, and I certainly  
25 understand the position of community physician and patient

1 who together wish to make the decision whether or not to use  
2 it. On the other hand, I think it is our obligation as a  
3 committee to make sure that full and accurate information as  
4 to toxicity at various doses is available.

5           Maybe I could digress for just a couple of minutes  
6 or seconds on a couple of issues that have been raised.  
7 First of all, how useful is serum creatinine to measure  
8 renal function? I think everybody is aware that the most  
9 precise measures are inulin clearance, which is clearly not  
10 clinically practical. It may not be readily appreciated  
11 that creatinine clearance is often used in the hospital  
12 setting is not terribly accurate and, actually, the Cock-  
13 Croft-Gault estimation of glomerular filtration is  
14 substantially better.

15           Having said that, if we use Cock-Croft-Gault that  
16 takes into account serum creatinine, patient age and weight,  
17 and imagine a 40-year old patient, a male weighing 72 kg, if  
18 he has a baseline creatinine of 1, his creatinine clearance  
19 is estimated at 100 ml/minute using that Cock-Croft-Gault.

20           If we imagine now that he develops toxicity such  
21 that his serum creatinine rises to 0.5, if you work that out  
22 his estimated GFR has fallen to 67. This is actually a  
23 geometric progression, not quite the logarithmic  
24 progression, but it is important to realize, and this is the  
25 point Dr. Feinberg was making earlier this morning, that

1 relatively modest changes in creatinine represent  
2 significant decrements in glomerular filtration. I know  
3 that the sponsor is acutely aware of this and certainly has  
4 set their limit relatively low.

5 I will point out for that same man that if his  
6 creatinine serum rose from 1 to 1.4, his clearance would  
7 still have dropped from 100 to 71. So, significant  
8 decrements in creatinine clearance can still come about from  
9 relatively modest changes in creatinine.

10 The second link point to this is that there is a  
11 certain amount of renal functional reserve that I think we  
12 all realized. That is, you can donate one kidney and the  
13 remain kidney hypertrophies and there is no change in  
14 glomerular filtration. At some point, as you pass 50-70  
15 percent of renal mass reduction, that ability to compensate,  
16 that is, that renal functional reserve has disappeared, and  
17 further insult, toxic insult or something else, has  
18 tremendous consequences.

19 In addition, there is a further point where  
20 glomerular filtration has fallen probably below 50 where, in  
21 some patients, an insidious process of progression renal  
22 insufficiency leading to end-stage renal disease goes  
23 forward.

24 So, the question is how do we understand the  
25 various changes in serum creatinine, not knowing in many

1 cases patient weight and age to be able to estimate  
2 creatinine GFR?

3 I guess, as I look at the data, I see that about  
4 half a percent of patients getting this drug develop acute  
5 renal failure requiring hemodialysis, and about 5 percent of  
6 patients, and here the number is a little bit hard to be  
7 sure of -- perhaps as high as 8 percent, perhaps somewhat  
8 lower than 5 percent but I will use 5 percent for now are  
9 going to be left with a fixed renal deficit in excess of 0.5  
10 of serum creatinine. That is a fall in our hypothetical  
11 patient from 100 to 70. What does that mean for that  
12 patient? I don't think that patient is at risk for  
13 progression to end-stage renal disease, and I think that is  
14 the good news. But I think we have to recognize that by  
15 having given up a certain amount of renal functional reserve  
16 that patient is at greater risk should they live long enough  
17 and need additional therapies, should they need cidofovir,  
18 should they need contrast as one of these patients here did  
19 receive, of developing acute renal failure. That is a  
20 certain definable risk. It is not an inalterable problem  
21 but it is something that needs to be weighed against the  
22 benefit.

23 Another related point is what do we say about the  
24 patient whose- creatinine goes up and then comes back down?  
25 Can we say that that patient is entirely back to normal?

1 Unfortunately, we can't say that that patient is or is not  
2 back to normal because of this issue of renal functional  
3 reserve being very hard to measure. So, I don't want to  
4 push this point too hard but I think in the back of our  
5 minds we have to worry a little bit about a drug for which  
6 50 percent, perhaps, of the population treated a year  
7 experiences significant rises in their creatinine even  
8 though most of them, 80 percent, 90 percent or 95 percent  
9 return back to normal.

10 So, in terms of the available safety data, what I  
11 would like to see would be, insofar as possible, complete  
12 follow-up of patients ideally after 48 weeks, which I see as  
13 the plan, 48 weeks of treatment and then 48 weeks of follow-  
14 up in the two proposed studies. I think that would give us  
15 a much stronger sense of do the final 5 percent get back to  
16 baseline, and they may or may not. As far as 30 mg that has  
17 been raised, clearly we need to know a lot more about the  
18 safety profile of that drug.

19 Now, in terms of the packaging information, we are  
20 being told that these patients are at increased risk for  
21 renal failure if they have an elevated creatinine of 1.5 or  
22 more and should be excluded. I would raise the issue for  
23 the FDA to consider and the committee to consider whether we  
24 should be using Cock-Croft-Gault there as well. Again to  
25 give you an example, if we had a 40-year old woman, weighing



1 60 kg, whose baseline creatinine is 1.4, she has glomerular  
2 filtration of 51 ml/minute. I would argue that is such a  
3 minimal level of renal function that that might not be a  
4 good patient to receive this medication.

5 In terms of the management plan, once renal  
6 dysfunction has appeared, I actually it was quite well done  
7 and quite well thought out. I thought the supplements  
8 seemed quite reasonable. I actually don't have a major  
9 problem with monthly monitoring. I realize that some  
10 patients do double their serum creatinine or drop their  
11 serum phosphate. I am not clear that there is a major risk  
12 to the patient. I am a little bit more concerned about a  
13 severe acidosis between monthly monitoring. In fact, we  
14 have no data about acidosis in study 417. But I am quite  
15 concerned about this issue of continuing a nephrotoxin, even  
16 at a low dose of 30 mg a day, in somebody who has  
17 established nephrotoxicity that is not returning to  
18 baseline, a patient who has a 0.2 or 0.3 increment. It is  
19 interesting that many of these patients were able to be  
20 treated through the episode, and I don't understand that but  
21 I think my own initial take is that I would not want to  
22 consider exposing a patient to a nephrotoxin, the same  
23 nephrotoxin that has caused damage, and certainly not until  
24 information on efficacy is there. I think I will stop at  
25 that point.

1 DR. HAMMER: Thank you very much for those  
2 comments. Dr. Verter?

3 DR. VERTER: I pretty much agree for question two  
4 with the comments of the previous three speakers, and I  
5 don't have any sense of the package insert.

6 DR. HAMMER: Thank you. Dr. Wong?

7 DR. WONG: I have nothing really to add.

8 DR. HAMMER: Dr. Lipsky?

9 DR. LIPSKY: On the issue of toxicity, I am a  
10 little concerned that, again, it is a one dose fits all. I  
11 think there are differences in exposure. We have a drug  
12 that is primarily eliminated by the kidney, and if one would  
13 think to amino-glycosides, is this the way you would handle  
14 amino-glycosides? This isn't amino-glycosides but it is  
15 another drug that accumulates in the proximal renal tubule,  
16 etc.

17 When you look at the curves of the time to  
18 problems with nephrotoxicity in the two doses, the  
19 inflection points or the changes are about the same, and one  
20 wonders if the exposure in the lower dose group in some of  
21 the patients is not comparable to the exposure in some of  
22 the patients in the higher dose group. Perhaps therapeutic  
23 monitoring could help in avoiding toxicity with this agent  
24 and understanding if there is a relationship between  
25 concentration dose and the subsequent development of

1 toxicity.

2           The other issue of reinstating the drug, well,  
3 if it is an accumulation problem are you just going to  
4 postpone the inevitable, realizing that there is a  
5 risk/benefit and the inevitable of not having the drug could  
6 be worse than kidney damage.

7           DR. HAMMER: Thank you. Dr. Masur?

8           DR. MASUR: I concur with the previous speakers,  
9 but I think Dr. Lipsky's point is an excellent point. It  
10 appears that there is so little known about the pathogenesis  
11 of the renal disease that exploring more a pharmacokinetic  
12 or pharmacodynamic analysis for toxicity might be very  
13 productive.

14           DR. HAMMER: Dr. Hamilton?

15           DR. HAMILTON: I too concur with my associates and  
16 their concerns about the renal toxicity, but would add that  
17 as a clinician taking care of patients and even as an  
18 investigator, frankly, it is not this level of toxicity that  
19 is of concern to me in this case; it is the efficacy.  
20 Heaven knows, we have learned to live with substantial  
21 toxicity when there were other issues more pressing at that  
22 time. Unfortunately, we don't have that efficacy at this  
23 moment. I will defer at that point.

24           DR. HAMMER: Thank you. Dr. Yogev?

25           DR. YOGEV: I don't think we have enough on

1 toxicity. If you look at the curve and how more patients  
2 develop a creatinine problem, it doesn't level off even at  
3 48 weeks. So, we need a much longer period of time to see  
4 that accumulating.

5           Interestingly enough, most of the toxicity -- 60-  
6 plus percent of the patients developed toxicity between week  
7 20-28 and one wonders should you add a little bit more  
8 closer monitoring at that specific period of time which, for  
9 some reason, is unique in the two studies that were  
10 presented. So, I think I need to see more. Many of the  
11 patients are going to use the amino-glycosides, the  
12 amphotericin B, and other drugs that are nephrotoxicity. Is  
13 there a synergistic effect, no effect? That is another  
14 safety issue which was not addressed and one would like to  
15 see.

16           DR. HAMMER: Thank you. Dr. Mathews?

17           DR. MATHEWS: Well, I agree with most of the  
18 people that spoke before about lack of long-term safety  
19 data, meaning beyond 48 weeks. On the other hand, I view  
20 this drug as sort of a bridge agent for people that need  
21 something in the short run that may not have the option of  
22 waiting for two years until the next generation comes along.  
23 The fact of the matter is that at least half of the people  
24 exposed to this drug at the doses currently used aren't  
25 going to be taking it for more than a year, based on the

1 toxicity and other reasons for dropping out. So, the short-  
2 term toxicity seems to be reasonably well characterized.  
3 You know, when you view it from a pragmatic point of view,  
4 who is need of the drug and how long might they need to be  
5 in need of it, I don't have as big a problem with it. If I  
6 put a patient on this, which I have many times, I would not  
7 expect that they are going to stay on it for much more than  
8 a year, at best, anyway.

9           With regard to their monitoring and toxicity  
10 management program, while it is well designed, I think there  
11 are a number of unanswered issues. For example, they talk  
12 about a 7-day window between use of adefovir and other  
13 nephrotoxic agents, but anybody who practices medicine  
14 realizes you may not have the luxury of a 'I-day window. If  
15 somebody on adefovir comes into the hospital with sepsis and  
16 has to be put on an amino-glycoside or amphotericin, there  
17 is no window. I don't know what the risk is of the drug in  
18 that setting. There are other agents that can affect renal  
19 function -- nonsteroidal anti-inflammatory drugs, ACE  
20 inhibitors. We haven't heard any discussion about those  
21 kinds of things. So, I think more would need to be done  
22 with the toxicity management to clarify very practical  
23 clinical issues.

24           DR. HAMMER: Thank you. Dr. Stanley?

25           DR. STANLEY: Yes, regarding the safety profile, I

1 too would like more long-term data on the nephrotoxicity,  
2 but also I keep going to the graph of study 417 and the  
3 continual dropouts of patients even from the 60 mg dose, and  
4 I just wonder what the nature of that is. Are there other  
5 toxicities or side effects that were just not adequately  
6 assessed? So, I think we still have a lot to learn about  
7 the safety profile of the 60 mg dose.

8 As far as the proposal for management, I do ask  
9 how did we come up with dose reduction instead of cessation  
10 of drug? Again, as someone said earlier, I have seen no  
11 data to support that recommendation. Monthly monitoring may  
12 allow some people to fall through the cracks, as the FDA's  
13 analysis pointed out, but I don't see much of a better  
14 alternative to monthly monitoring.

15 I would point out that that is going to be  
16 problematic for some of our patients who are perhaps ADAP or  
17 Medicaid patients who, to maximize their medication usage,  
18 have to rely on getting multiple months at once. So, I  
19 think it is going to pose just some logistical problems for  
20 certain patients that need to be considered, but I don't see  
21 a better alternative at this point.

22 DR. HAMMER: Thank you. Dr. Bertino?

23 DR. BERTINO: I would concur with many members of  
24 the committee that I would like to see more data on the 60  
25 mg dose from a safety standpoint. I am actually not even

1 going to comment about nephrotoxicity but talk about some  
2 other things. Carnitine supplementation, for example, is  
3 recommended and I am kind of sitting here, thinking, well,  
4 why? Is there something that has been shown in terms of  
5 carnitine levels drops so that we need to supplement  
6 carnitine, etc? Does that affect efficacy of the drug? We  
7 don't really have any of that information at hand.

8           It appears that the decision to either reduce the  
9 dose or stop the drug -- I am not quite sure from the 60 mg  
10 to 30 mg dosage reduction that we saw data today that  
11 supported that. So, I don't think that I could support that  
12 in the labeling either.

13           In terms of the sponsor's proposal for renal  
14 toxicity management, there certainly is a precedent for this  
15 kind of monthly monitoring and that is with the drug  
16 clozapine, where patients are monitored very regularly -- in  
17 fact, I think it is more than monthly, for white blood cell  
18 count, and then once the white count is obtained it is fed  
19 back to the pharmacy and the drug is dispensed. We are kind  
20 of facing a different situation here, however, because if a  
21 patient doesn't get their antiretroviral agent, or if they  
22 decide they are not going to get any of their antiretroviral  
23 agents for whatever reason, because they don't want to go in  
24 for monitoring or whatever, that I think is probably at  
25 least as problematic, maybe more problematic than, you know,

1 missing your clozapine for a few days.

2           So, I don't have a better way to suggest doing it.  
3 I think it is pretty ambitious of the sponsor to suggest  
4 this type of management. I think there are a lot of other  
5 questions having to do with financial considerations that I  
6 know the FDA doesn't consider but I think a lot of us at  
7 this table are thinking about in terms of the monitoring and  
8 getting multiple months worth of drugs, and things like  
9 that. So, I think it is an interesting proposal. It will  
10 be interesting how it will work in practice, however,.

11           DR. HAMMER: Thank you. A couple of comments  
12 first with respect to question two, the safety profile of 60  
13 mg of adefovir being adequately characterized, I would like  
14 to just dissect this quickly. First, I think the  
15 description of it, yes, has been adequately characterized,  
16 and I think the time of onset is very clearly evident from  
17 the time graphs that we have seen with the inflection points  
18 between weeks 24 and 28. I think what is not clearly  
19 characterized yet is its full incidence. Of course, that  
20 depends on your definitions and your thresholds and, as has  
21 been already stated, where those curves will ultimately end  
22 up and study to study differences make it uncertain. But  
23 that is less of a concern to me because with ongoing data  
24 collection, one would find out about that I think.

25           I think the one open question still, because of



1 the lack of length of follow-up, is the reversibility. So,  
2 I personally have no problems with the description of it for  
3 physicians and patients with the clear time to onset, and I  
4 think we know the ballpark incidence but we may not know the  
5 final incidence per se, but the reversibility and the  
6 totality of that reversibility over time is still a  
7 question. By itself, however, this does not dissuade from  
8 the drug's use. I think it has been well stated by my  
9 colleagues about the fact that we have dealt with toxicity-  
10 efficacy ratios before in other drugs, and when the efficacy  
11 aspects of it are there we can handle toxicities.

12 I think we should also -- at least some of us --  
13 be internally consistent if in other venues we are stating  
14 that HIV disease should be managed by specialists in concert  
15 with well-informed patients. Then I think that toxicity  
16 such as this that has been fairly well characterized, even  
17 if its basic mechanism is not fully understood, can be  
18 handled by educated physicians. It is just another  
19 statement that, in fact, this disease should be managed by  
20 people who know what they are doing in concert with  
21 excellent patient education.

22 As far as the adequacy and feasibility of the  
23 sponsor's proposal for renal toxicity management, the  
24 sponsor has made a very commendable effort in trying to  
25 detail this to get at what the best predictors are of full-

1 blown PRTD syndromes, and teasing that out as far as  
2 creatinine elevations and phosphate declines, and the  
3 monthly monitoring I think, in a practical sense -- one  
4 really can't do better than that and one has to realize that  
5 these are just guidelines for management, and there will be  
6 variability in their practice and there is nothing that can  
7 be stated in a guideline that will be 100 percent adhered to  
8 by 100 of physicians and 100 percent of patients. So, I  
9 think the general guidelines are very well thought out. My  
10 one reservation has been stated before, and that is that we  
11 have no data on the efficacy of the 30 mg, and my personal  
12 reaction would be, if one starts seeing nephrotoxicity to  
13 remove the nephrotoxin until there is data to suggest that  
14 30 mg is efficacious.

15           Let's move on to this fourth question for the  
16 committee. I will read the question itself for the record:  
17 Do the provided data establish that adefovir 60 mg is safe  
18 and effective for the treatment of HIV infection? I will  
19 defer A or B because it depends on what we say. I would ask  
20 the committee members to comment on this but to reserve the  
21 vote. They can state whatever they wish but we will take a  
22 formal vote after everyone has a chance to make a comment,  
23 and then, after the vote, we will deal with A or B as put  
24 forward to us by the agency. So, I would put question four  
25 to Dr. Bertino.

1 DR. BERTINO: No on efficacy. I think we know the  
2 safety profile somewhat but I think we would like to know  
3 more.

4 DR. HAMMER: Dr. Stanley?

5 DR. STANLEY: No.

6 DR. HAMMER: Dr. Mathews?

7 DR. MATHEWS: Yes.

8 DR. HAMMER: Dr. Yogev?

9 DR. YOGEV: No.

10 DR. HAMMER: Dr. Hamilton?

11 DR. HAMILTON: No.

12 DR. HAMMER: I think we are taking the vote. Dr.

13 Masur?

14 DR. MASUR: No.

15 DR. LIPSKY: No.

16 DR. HAMMER: Do you want to make comments?

17 DR. WONG: I will make a comment. Had this come  
18 at 120 mg I would have voted yes but at 60 mg no.

19 DR. HAMMER: Dr. Verter?

20 DR. VERTER: No.

21 DR. HAMMER: Dr. Kopp?

22 DR. KOPP: No.

23 DR. HAMMER: Dr. Kimmel?

24 DR. KIMMEL: I am not supposed to vote.

25 DR. HAMMER: Okay. Mr. Schouten?

1           MR. SCHOUTEN: I will make a comment first. There  
2 clearly is a niche where some people are benefiting from  
3 this drug and I think that patients are being penalized  
4 because of the poor design of the trial, 417, in my opinion.  
5 So, I am torn about what the FDA should do, and we have a  
6 situation where a drug is probably kind of a gap filler for  
7 a small group of patients who have no other options, and it  
8 works against a class of virus so there is evidence that it  
9 works against a class of virus that is resistant to AZT and  
10 3TC.

11           So, I think if there is some way that this drug  
12 could be licensed with the caveat that it be used with AZT,  
13 with 3TC in people with documented 215 or AZT mutations and  
14 the 184 mutation, I think in that setting it is going to  
15 benefit people. But if you are asking about whether or not  
16 there is proven efficacy that this drug works based on the  
17 data presented at 60 mg in the trials we are looking at,  
18 then it doesn't.

19           DR. HAMMER: I will just make a few comments.  
20 First, from the perspective of this committee, my view is  
21 that this committee has tried its hardest actually to  
22 improve access for drugs, and to look for ways to facilitate  
23 getting the sponsor and the agency together to get drugs out  
24 in the arena because I think everybody here realizes the  
25 need for additional therapies and that we are not where we

1 want to be.

2 I also think that the sponsor deserves a lot of  
3 credit for trying to develop a drug for a treatment  
4 experienced population, particularly, obviously, with a lot  
5 of drug resistance, and for trying to exploit something that  
6 is at least intriguing to us, and that is the resistance  
7 mutation interactions, and for promoting an early expanded  
8 access program.

9 We haven't talked about it too much in this  
10 discussion but, in fact, the virology here -- if one  
11 accepts, as some of us do, the activity of 120 mg and  
12 accepts some of the in vitro data vis-a-vis hyper-  
13 susceptibility with the 184 mutation and the 408 virology  
14 substudy, is one area that is of particular interest. One  
15 wishes that that number were greater. One wishes that there  
16 had been a trial that actually randomized patients with the  
17 184 at baseline to various interventions to try to prove  
18 this. One would also liked to have seen some similar data  
19 at the 60 mg dose per se in comparison to the 408 substudy.

20 I also have to mention that coming into this the  
21 virology issues with adefovir and activity against isolates  
22 with the 184 mutation and the niche that that holds, that  
23 the agency's presentation in that regard casts some doubt on  
24 one aspect of that which creates overall some doubt about  
25 full interpretation. So, again, it is an area that is

1 intriguing. I wish that the fact were clear-cut in that  
2 regard, but additional data are necessary.

3 I would echo what Dr. Wong just mentioned,  
4 although the toxicity make it incumbent upon the sponsor to  
5 reduce the dose from 120 mg to 60 mg, the vote on question  
6 four would have been substantially easier for me personally  
7 at 120 mg than it is at 60 mg.

8 With that said, I think we should go ahead and  
9 vote. I will read the question again and list the voting  
10 members. Do the provided data establish that adefovir 60 mg  
11 is safe and effective for the treatment of HIV infection?

12 The voting members are Drs. Masur, Lipsky,  
13 Hamilton, Pomerantz, Wong, Yogev, Mathews, Stanely,  
14 Feinberg, El-Sadr, Verter, Bertino, Kopp and me.

15 So, if you are voting yes on question four, please  
16 raise your hand.

17 [One hand raised]

18 One vote yes. Those voting no on question four,  
19 please raise your hand.

20 [Show of hands]

21 I would state for the record that Drs. Feinberg,  
22 El-Sadr and Pomerantz left their written votes as no. So,  
23 the final vote is one yes and thirteen no.

24 We will then go on to a discussion of 4A. If not  
25 -- and that is the consensus of the committee -- what

1 additional data should be provided prior to reconsideration  
2 of this application for approval?

3           Rather than going around point by point, person by  
4 person, I will open this up for those who want to comment.

5 Dr. Bertino?

6           DR. BERTINO: Well, I think it will be very  
7 important to have drug interaction information in patients  
8 with HIV disease, particularly in this case I am curious  
9 about things like saquinavir, using multiple doses of both  
10 antiretrovirals, indinavir and whatever other antiretroviral  
11 agents, and also adjunctive agents that are used for OIs,  
12 things like that.

13           I also think that more data in terms of  
14 pharmacokinetics of these agents in HIV patients is  
15 important. I think that we saw some data looking at sex and  
16 at ethnicity earlier, and it was nice to see that data. But  
17 it is becoming pretty clear that HIV patients are not the  
18 same as normal volunteers, and one of the speculations is  
19 that it is because of cytokine production. So, there **may** be  
20 a need, if you are going to do drug interaction studies to  
21 even stratify by viral load, if you want to use that as a  
22 surrogate, or actually measure cytokines, which is being  
23 done in some centers now because pharmacokinetics and drug  
24 interactions may change over time as viral load drops.

25 Pharmacokinetics in children -- I was kind of left with what

1 exactly -- under the age of two what kind of pharmacokinetic  
2 data was available.

3 I wonder if the drug shouldn't be dosed on a  
4 milligram/kilogram basis. I know that may be considered the  
5 death knell for a drug but, as Dr. Lipsky pointed out, we  
6 may be seeing a dose-response effect and the reason why the  
7 120 mg and 60 mg curves bump up at a fairly similar point  
8 for nephrotoxicity may be due to exposure. So, should we  
9 look at dosing the drug on a milligram/kilogram basis?

10 Then, finally, how should toxicity be handled,  
11 nephrotoxicity? Should you reduce the dose? Should you  
12 stop the drug? Should you supplement? Can you treat  
13 through it, etc.?

14 DR. STANLEY: As we have already said many times,  
15 we need a placebo-controlled study of 60 mg as well as the  
16 30 mg. I think it needs to be done in the appropriate  
17 populations that this drug is going to be targeted for.

18 I would also ask for more evaluation of the  
19 potential drug interactions. I think it is very suspicious  
20 -- the saquinavir and delavirdine results with 120. Perhaps  
21 we would avoid that with the 60 mg but I think we need to  
22 see more studies on drug interactions.

23 Finally, in addition to what has already been  
24 mentioned, we need to look at the effect of the 60 mg and 30  
25 mg doses on the resistant viruses. Do they have the same



1 apparently positive results as the 120 mg dose does? So, I  
2 think we need some good virologic studies at those lower  
3 doses.

4 I think that the two proposed 415 and 458 are good  
5 studies, and we need the data from those studies. That  
6 would help tremendously I think.

7 DR. HAMMER: Dr. Mathews, did you have a comment?

8 DR. MATHEWS: You know, it is not so obvious to me  
9 how, in the target population of treatment advanced  
10 patients, you can cleanly do a placebo-controlled study that  
11 isn't going to have the same problems that, for example, the  
12 417 study did, where you are going to be comparing it to  
13 other drugs that are also active, and not still have the  
14 same problems of teasing out confounding by putative drug  
15 interactions. So, if any of you have ideas on exactly how  
16 this would work -- I am just at a loss to see how that would  
17 work.

18 Secondly, I think increasingly these kinds of  
19 studies are going to have to have baseline susceptibility  
20 known in advance, and not this business of saving the  
21 samples and running them later. I mean, this is not how we  
22 practice, particularly for the nucleoside analogs, this drug  
23 and others like it. I think these things have to be known  
24 up front, and perhaps that is a topic for the discussion  
25 tomorrow and the next day.

1 DR. HAMMER: Comments? Dr. Yogev?

2 DR. YOGEV: Very quick, I think the company should  
3 better define what experienced patients we are talking  
4 about, and really find the right niche and not such a vague  
5 experienced population because of the toxicity, and I would  
6 love to see them also doing some work on pregnant women,  
7 especially with a drug which is taken once day which,  
8 hopefully, will also be cheaper. Thinking about the  
9 international implication of that, maybe they should look  
10 into concentrations of the drug in breast milk also as part  
11 of that.

12 DR. HAMMER: Other comments or suggestions? Dr.  
13 Masur?

14 DR. MASUR: I am glad Chris brought up the issue  
15 of looking at efficacy because I think it is no small feat  
16 to look at efficacy in this kind of population with a single  
17 drug. But I think, as Joe and others said, looking at  
18 toxicity is something which can certainly be better defined.  
19 I guess I would be more comfortable with this drug if it was  
20 clear what predicted or correlated with toxicity and how  
21 reversible it was if there were less data missing, and it  
22 would appear that that data will be forthcoming.

23 DR. HAMMER: I would just mention a couple of  
24 things. I agree completely that the study design issues  
25 here are hugely challenging and teasing out the activity of

1 a single drug is easy to say in the context of this  
2 committee and hard to do in practice. But there are a  
3 couple of things that one could think about in relation to  
4 this drug. One is that when it is added as a fourth drug to  
5 a three-drug regimen, while we didn't see data that that  
6 made a difference, one could look at early slopes of decline  
7 of RNA if frequently monitored and at least get a handle on  
8 whether there is a greater potency to the regimen compared  
9 to a very acceptable standard of care regimen since depth  
10 and rate of decline are predictive of durability. So, one  
11 could have an inference there.

12 I think Dr. Feinberg made the point, since this  
13 drug gets selectively stopped often -- in other toxicity  
14 areas, because of threats of resistance, we usually stop  
15 everything. This is a drug where often it is stopped in  
16 isolation and where that is the case, in a more formal  
17 analysis of what is truly happening to viral rebound, if it  
18 is there, when this drug is stopped, would be an indirect  
19 measure but also a helpful measure.

20 I also think that a prospective randomized trial  
21 based on resistance at baseline would have been terrific to  
22 see here because, again, the virology could drive the  
23 decision-making around this drug. The point, to me, is not  
24 just that it has a niche but it has a niche for a particular  
25 reason because of the in vitro data and the 408 virology

1   substudy that suggest that it is active against viruses  
2   carrying the 184.   One could define a trial based on  
3   plus/minus 184 at baseline, then randomized to whether  
4   patients need 3TC or something to maintain the 184 in the  
5   presence of this.   Then with or without an adefovir-  
6   containing regimen, again seeing whether you are defining  
7   something where adefovir gives you an extra margin of  
8   efficacy.   So, I think the niche, which is an overused word  
9   today, that this drug has allows you to define a study that  
10  is virologically based that allows you to look at efficacy.

11           I think the tortured views that the committee has  
12  expressed today are, I think, based on the fact that a lot  
13  of us feel there is something clearly here.   It may be that  
14  with other generation drugs it will be much more clearly  
15  there.   But one would have liked and wanted to have seen the  
16  data to really believe it.   I think that one could design a  
17  study that is not too large that defines that, and that  
18  might have been more convincing to a majority of the  
19  committee.   But I think that some of those designs that are  
20  virologically based can help us tease out the efficacy, and  
21  the safety issues have been so well described by others that  
22  I won't comment any further on that.

23           DR. WONG:   I guess just to reiterate, I think that  
24  the safety issues, the pharmacology, the pharmacokinetics,  
25  all of those things -- of course, we need my information but

1 in my mind the problem was in efficacy of the 60 mg dose.  
2 So, if the sponsor could come back demonstrating that the 60  
3 mg dose is efficacious, that would settle it for me.

4 DR. HAMMER: I concur with those comments. I  
5 would also just add that the assay now seems to be available  
6 and looked at in primates, a handle on adefovir diphosphate  
7 levels at different doses in peripheral blood mononuclear  
8 cells would be very interesting to see whether, in fact,  
9 there is a dose response or not a dose response with at  
10 least relationship to intracellular diphosphate levels and  
11 the RNA responses.

12 MR. SCHOUTEN: I guess my comments are going to  
13 relate to the drug-drug-drug interactions and the complexity  
14 of assessing that. I don't have any easy solution for that  
15 but with a drug that has apparently a fairly flat dose-  
16 response curve and an intracellular activation is blood PK  
17 data adequate to reassure us that there is not an adverse  
18 interaction, and that is a challenge. Particularly for a  
19 drug whose purported indication would be for deep salvage,  
20 that is even more of a challenge.

21 DR. LIPSKY: I think I heard that the demand for  
22 the expanded use was 400 a month, and you would think, or it  
23 should be obvious that that is a desire for efficacy and  
24 that one should be able to design a study based on that need  
25 and that desire to more formally answer that question.

1 DR. HAMMER: Any other comments? Dr. Kimmel?

2 DR. KIMMEL: I think that the data on using the  
3 drug after nephrotoxicity is established is very important,  
4 and I think renal and virologic parameters should be  
5 investigated, and that might give a lot of comfort to  
6 members of the committee.

7 DR. HAMMER: There is one last question which I  
8 think we probably have addressed in the ranging comments  
9 that we have had throughout the afternoon, but for the  
10 record I will read it: What additional recommendations do  
11 you have for further investigation of adefovir for HIV?

12 Does anyone have a comment on that? I think one  
13 comment that **was** made earlier is in the co-infected  
14 populations. I think that should be restated for the  
15 record. Another very important population is HBV-HIV CO-  
16 infected individuals.

17 Seeing no hands raised, I would ask Dr. Jolson  
18 whether there are other issues or clarifications you would  
19 like the committee to discuss?

20 DR. JOLSON: Maybe I could just make a quick  
21 comment because I think that a meeting like this is  
22 difficult for everybody involved, and I think it has been a  
23 difficult application for the committee to consider. It has  
24 also been a difficult application for our team **as** well to  
25 consider. And, I think that the comments that the patients

1 made at the open public hearing -- it is hard not to take  
2 that to heart, as well as the size of the expanded access  
3 program which certainly makes it clear to us that there is a  
4 sizeable population out there in need of more options.

5           Hopefully, the message that I am hearing is that  
6 there is something constructive out of this. It sounds like  
7 the major issue, as I understand it, is really the standard  
8 of efficacy being met in terms of definitively establishing  
9 the 60 mg dose and its activity, and that with that type of  
10 data, as well as with some of the additional ancillary  
11 issues considered, the committee would then feel it  
12 appropriate to reconsider the application.

13           DR. HAMMER: If I could speak for the committee,  
14 and please feel free to interrupt if you disagree, although  
15 I think there was split opinion on question one, I think the  
16 consensus of the committee is that there truly is something  
17 here with this drug; that the desire of this committee was  
18 to actually believe that there were efficacy data there and  
19 to see the data in a fashion that one could feel absolutely  
20 comfortable with.

21           I do think the sense of the committee is that this  
22 should not be a closed issue, that further studies and  
23 investigation should be performed, and that we applaud the  
24 studies that were started because we think that some of  
25 those will give us additional answers, and that whatever

1 additional information can come forward clearly to establish  
2 the 60 mg dose as efficacious is the key issue here because  
3 that is where the indication is, and the bulk of the  
4 information is at 120 but we need efficacy data at 60.

5           Although much was discussed about what we still  
6 don't know about nephrotoxicity, it relates to data  
7 collection that is in process or will come about, and in  
8 management of it and in patient and physician education. I  
9 would at least personally say I don't see that as the show-  
10 stopper. I see the issue here coming in with clear-cut  
11 demonstration of 60 mg efficacy data that the agency and the  
12 sponsor can agree on, such that if it comes before this  
13 committee again we have a clearer focus that there is  
14 something there. Some of us tried to see it but it was not  
15 fully clear to us.

16           So, I think what you are taking away is that, in  
17 fact, we would encourage more information and  
18 reconsideration of this agent, specifically with convincing  
19 information about the 60 mg dose, and however quickly one  
20 can get there is what we would like to see because I think  
21 it is obvious that this committee shares the thoughts that  
22 were expressed at the open public hearing that we are not  
23 where we want to be and that options should be out there for  
24 patients and physicians, and that is the position this  
25 committee has taken before.



1           We have an obligation to look at the data and  
2 critically review it. Also, under the issues of accelerated  
3 approval, there are issues of critically reviewing the  
4 information and we are dealing with this individual agent  
5 but also, in our minds, we are looking at the history of  
6 where we have come from and where we are going in drug  
7 approvals for this disease, and critical data analysis is  
8 clearly part of that.

9           So, we would love to see a study that is  
10 unequivocal, or at least marginally equivocal, that both the  
11 sponsor and the agency can agree shows activity at the 60 mg  
12 dose.

13           Anyone disagree with that lengthy response? On  
14 that note then, I would like to thank the sponsor, Gilead  
15 Sciences. I would like to thank the guests and consultants  
16 on the committee and the members of the committee and the  
17 agency, and particularly the FDA presentations today which  
18 were clear, and for the audience participation. Thank you.  
19 The meeting is adjourned.

20           [Whereupon, at 5:55 p.m., the proceedings were  
21 adjourned, to resume at 8:30 a.m., Tuesday, November 2,  
22 1991

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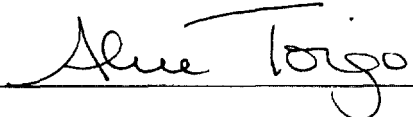
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## *C E R T I F I C A T E*

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

  
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