

1 DR. LIPICKY: Well, we have not seen the data.

2 It exists but you haven't seen a review.

3 DR. TEMPLE: No.

4 DR. LIPICKY: You haven't seen a table. You  
5 haven't seen a figure. I haven't see a table. I haven't  
6 seen a figure. I haven't seen any pros. I haven't talked  
7 to anybody who has actually opened the volume. So, we  
8 don't know any more about RENAAL than is in the New England  
9 Journal.

10 DR. TEMPLE: Right. You could tell us what you  
11 would think, for example, if after review, that was thought  
12 to be a solid study. We can't tell you that we know that.  
13 But you could say that. Obviously that might not affect  
14 your conclusion because you wouldn't know.

15 But it raises the whole question of what, which  
16 is absolutely not settled, except I did tell you that we  
17 have behaved as if ACE inhibitors share common properties  
18 when we deal with congestive heart failure. And I would go  
19 further and say the beta-blocker approvals probably all  
20 reflect the fact that other drugs of the same class have  
21 had that effect.

22 So, you can tell us how you're thinking of it.

23 I don't know that fits into a vote exactly.

24 DR. FLEMING: Well, in fact, you have asked us  
25 this structured set of questions. We have gone through

1 question 12, which basically is based on the two trials and  
2 prior expectations from the captopril study, what was our  
3 judgment. Now in question 13, you're saying is there other  
4 relevant information. I don't have a problem with your  
5 asking the committee. I understand why you might want to  
6 ask the committee are there other sources of data that we  
7 would advise you should look at when you think about your  
8 final judgment.

9                   But I don't understand why you're going to  
10 press to question 14 and then say, now I want you folks to  
11 vote on that. That's an entirely different perspective.  
12 Why are you asking us to do any more now than suggest  
13 additional sources of information that you should think  
14 about?

15                   DR. TEMPLE: First of all, some people have,  
16 without thinking about those other studies, reached the  
17 conclusion that the answer is one way or another. So, you  
18 don't necessarily have to incorporate that. But you might  
19 want to tell us I'm at the edge. I'd be convinced if you  
20 looked at that study and found it satisfactory. You can  
21 tell us whatever you want. It isn't only the vote. We  
22 listen to the text also. It would be of considerable  
23 interest to me to know if you thought that a favorable  
24 finding in a closely related drug should be taken as the  
25 priors or the other evidence or whatever. And we can worry

1 about getting access to other data, and then we can also  
2 worry about whether we're violating a company's proprietary  
3 interest and a wide variety of other interesting questions  
4 that we're not ready to talk about here.

5 DR. LIPICKY: There are people within the  
6 agency who tell us not to ask questions where the answer is  
7 obvious, and to me the obvious answer to this question  
8 would be, of course, not. You're insulting my intelligence  
9 by asking me. Sometimes it's useful to ask questions like  
10 that so that we can get your reaction. But here we're  
11 being told now, because we asked questions we probably  
12 shouldn't have asked, that you know, well, the captopril  
13 study tips me over. Well, then it's fair to say, what else  
14 would tip you over?

15 DR. BORER: As the hour is moving on here,  
16 question 14 -- 15 is going to require some discussion I  
17 think. But 14 says, should irbesartan be approved for  
18 treatment of nephropathy in type 2 diabetes? Prior to 13,  
19 there were 4 yes votes already. So, just to deal with the  
20 time issue, I think I understood Blase to say that at 14 he  
21 would change his previous vote, but for the record, what's  
22 your vote now, Blase?

23 DR. CARABELLO: That is correct. Yes.

24 DR. BORER: So, now we have 5.

25 There are six other committee members who have

1 not been convinced by these data, and so I'm going to ask  
2 to go through each of those six. Should irbesartan be  
3 approved for the treatment of nephropathy in hypertensive  
4 or non-hypertensive patients with type 2 diabetes?  
5 Beverly?

6 DR. LORELL: For the issue of diabetic  
7 nephropathy in hypertensive patients, my answer would still  
8 be no.

9 DR. CUNNINGHAM: No.

10 DR. BORER: Mike?

11 DR. ARTMAN: No.

12 DR. BORER: Tom?

13 DR. FLEMING: I encourage the FDA to look at  
14 all information that they would have access to that they  
15 judge to be relevant.

16 I can't go beyond question 12 without specific  
17 data put before us with a judgment and with a good insight  
18 that we have a level of understanding of that data  
19 comparable to our level of understanding of the two trials  
20 here. My answer is no.

21 DR. BORER: Steve?

22 DR. NISSEN: My answer is also no. And I  
23 really do need to say something here, and that is the  
24 reason that I don't want us to consider the RENAAL data is  
25 there were things that came out in the discussion of the

1 IDNT data that I didn't know from reading the publication.  
2 For example, the cardiovascular endpoints are not in the  
3 New England Journal of Medicine publication. Those  
4 individual endpoints were very persuasive to me. I don't  
5 know as a fact that there aren't things in the RENAAL data  
6 that we haven't seen yet that would be very negative in my  
7 view. So, my answer is still no. I can't consider a study  
8 that isn't before us.

9 DR. BORER: Alan?

10 DR. HIRSCH: Well, no surprise based on my  
11 prior comments. No. But I would, since the text is read,  
12 strongly encourage the FDA to gain whatever access to data  
13 sets that exist that would permit us to look at this issue  
14 again, if that's possible.

15 DR. TEMPLE: I just want to be sure I  
16 understand the last couple of comments, and perhaps other  
17 people have the same sense. We have no idea whether we can  
18 get the two companies on the same stage or sort of steal  
19 one's data to use in the other. Let's leave all that  
20 aside.

21 What I guess I hear you saying is that some of  
22 you are not so convinced by information about captopril in  
23 a different population, but you might find independent  
24 studies of the same drug class in a very similar population  
25 more persuasive.

1 DR. HIRSCH: Yes, and I'll just try to  
2 summarize my feelings and maybe speak for others here.  
3 This is a very major national clinical problem. We're all  
4 seeing a signal of efficacy. We are all very close to the  
5 edge, but we're not quite there. So, whatever we can get  
6 that brings us closer to a decision would be great.

7 DR. BORER: Before we go on to number 15, which  
8 is the last question, can I ask if anyone has any comments  
9 about data that could be perhaps presented to the FDA and  
10 if they were presented to you would be useful over and  
11 above issues about other drugs and what have you. What,  
12 for example, would you think if the company was able now  
13 retrospectively to go back and determine cardiovascular  
14 events in the patients after cardiovascular events were no  
15 longer being counted? And what if the differences sort of  
16 evaporated? Would that be compelling to anyone? Would you  
17 like to see that?

18 DR. LORELL: Yes.

19 DR. BORER: Okay. So, that's one type of  
20 information that might be useful if the FDA is not  
21 convinced by the data that exists.

22 There may be others. For example, although Tom  
23 suggested that he accepts the creatinine of 6.0, as I do,  
24 perhaps if we asked the company to come back with the  
25 actual numbers of people who went on to dialysis or

1 transplant and the time at which they did that to confirm  
2 the importance of the creatinine level, would that be  
3 useful to anyone?

4 DR. LORELL: Yes.

5 DR. BORER: Okay, so that would be too. So,  
6 there may be some additional data that exists that might be  
7 helpful to the FDA in its final deliberations.

8 Having said that, do the results of the  
9 irbesartan development program in type 2 diabetic  
10 nephropathy support the use of proteinuria as a surrogate  
11 for clinical benefit? And we need everybody to say  
12 something about that. JoAnn?

13 DR. LINDENFELD: I don't think the data quite  
14 support the use of proteinuria at this point for a couple  
15 of reasons. One, I think that we don't have any idea of  
16 how much reduction in proteinuria is clinically important.  
17 I mean, if you saw a 10 percent reduction, would that  
18 really lead to some sort of realistic clinical change? I  
19 don't know the answer to that. So, I'm not ready to say  
20 that yet.

21 DR. BORER: Let's start on this side of the  
22 table with the nephrology contingent. Dr. Brem, what do  
23 you think of that? Do the results of the irbesartan  
24 development program in type 2 diabetic nephropathy support  
25 the use of proteinuria as a surrogate for clinical benefit?

1 DR. BREM: I was just talking to Dr. Temple  
2 about the very same issue. For a nephrologist, I believe  
3 that it does. And I read the FDA commentary, and I suppose  
4 by itself, in the absence of changes in GFR to correlate,  
5 it wouldn't. But I believe that it does. So, as a  
6 nephrologist I think it does, and if they looked at it  
7 correctly, it would correlate with a change in GFR. One  
8 thing that would be very helpful and supportive is if the  
9 company had similar data or would be able to retrieve that  
10 information to demonstrate the connection between  
11 development of proteinuria and change in GFR; that would be  
12 a very strong selling point.

13 DR. BORER: I'm sorry, Tom. Go ahead.

14 DR. FLEMING: I just wanted to clarify to make  
15 sure that at least I'm understanding the question. There  
16 are at least two different questions you could ask. One  
17 is, is proteinuria a correlate for subsequent clinical  
18 endpoints? Or there is the much more complicated question,  
19 is a treatment-induced effect on proteinuria an adequately  
20 reliable predictor of a treatment-induced effect on long-  
21 term clinical endpoints, that simply the demonstration of  
22 the effect on proteinuria is adequate evidence of an effect  
23 on the clinical endpoint? Which is what I would typically  
24 think of as the surrogate. Are you asking the first  
25 question or the second or both?



1 DR. LIPICKY: We're asking the second question  
2 only. Is it a surrogate? That is, proteinuria would be  
3 good enough. You see that proteinuria goes away and you  
4 say that people aren't going to get transplanted or have  
5 dialysis.

6 DR. TEMPLE: We believe a lot of nephrologists,  
7 as you've just heard, believe that proteinuria is an  
8 indicator of the fundamental structure of the kidney going  
9 down the tubes, and we have a lot of people who are asking  
10 us to use that as an endpoint because it's a very  
11 accessible endpoint and it occurs early and you don't do  
12 harm to people. So, that's a very important question.

13 DR. FLEMING: And that's the first issue. And  
14 there's a myriad of natural history data, and Dr. Lewis and  
15 others have clearly discussed the relationship that is  
16 establishing this as an important biological step along the  
17 cascade of events, such that in natural history, it's a  
18 correlate.

19 But we have a myriad of correlates across all  
20 disease areas, the vast majority of which are not  
21 established to be surrogates, and those that are typically  
22 are done so after extensive clinical experience where one  
23 is looking at the relationships of treatment-induced  
24 effects on the marker and the predictiveness of those  
25 effects on the clinical endpoint.

1                   We didn't even get from this study evidence of  
2 whether there was a relationship with effects on  
3 proteinuria to effects on filtration rate, much less the  
4 ultimate clinical endpoint. So, how does this study begin  
5 to provide us evidence as to whether we don't just have a  
6 correlate but we truly have a replacement endpoint  
7 surrogate?

8                   DR. TEMPLE: Well, don't yell. Just say no.

9                   (Laughter.)

10                  DR. BORER: We have his vote now.

11                  Dr. Kopp.

12                  DR. KOPP: You specifically asked about  
13 diabetes, but I'll make the first point that if you were  
14 looking at other diseases, a complete remission I think  
15 would be acceptable, that is, somebody with a disease like  
16 minimal change that you had an agent that could put people  
17 into complete remission, I think most nephrologists would  
18 be convinced that a sustained remission, as defined by no  
19 proteinuria, would be evidence of benefit.

20                  How about in diabetes? I guess if you had an  
21 agent that put somebody into complete remission, no  
22 proteinuria, who previously had proteinuria and that was  
23 sustained, I would find that pretty convincing.

24                  The problem comes from what you mentioned,  
25 JoAnn, which is how about a 50 percent decrement, which is

1 the typical effect of ACE inhibitors. Then how about a 30  
2 percent? Then how about a 25 percent? And as we said  
3 earlier, we don't have a graded spectrum of risk table that  
4 allows us to evaluate that. So, I think that's where  
5 you're coming from.

6                   And I have to say by itself, I don't find it  
7 adequate. Now, I did find it adequate in the second study,  
8 IRMA 2, because I had another study that had a GFR measure,  
9 and in that setting, it's supportive. But by itself as the  
10 only measure, short of a complete remission, I have trouble  
11 accepting it.

12                   DR. LORELL: I agree with that. I think the  
13 evidence is very compelling that proteinuria is both a  
14 measure and may even play a role in the progression of  
15 diabetic nephropathy. I don't think that that is  
16 sufficient to use it as an endpoint for approval or  
17 disapproval of a drug.

18                   I think a very poignant example in the recent  
19 cardiovascular and even perhaps cardiovascular-renal world  
20 is the use of estrogen replacement therapy where it was  
21 argued for a long time that the improvement in lipid  
22 profiles that were seen demographically and in trials could  
23 be used as a surrogate marker to indicate expected  
24 improvement in major cardiovascular events. And actual  
25 trials that asked that question have given a striking

1 answer in the other direction.

2 DR. BORER: Dr. Cunningham.

3 DR. CUNNINGHAM: I think I don't actually know,  
4 so I cannot say yes, but I don't know if I can no either.  
5 So, you'll have to deal with that.

6 DR. BORER: It's an abstain.

7 Mike?

8 DR. ARTMAN: I would say no and leave it at  
9 that.

10 DR. BORER: Tom, I think you already said no.

11 Blase?

12 DR. CARABELLO: I think I also would like to be  
13 fair and simply say I don't know.

14 DR. NISSEN: No question that proteinuria is a  
15 bad thing, but the question being asked is do we know that  
16 a drug that reduces proteinuria is going to have a  
17 consistent, reproducible effect on hard endpoints. I would  
18 want to see several trials, maybe even with different  
19 classes of drugs, showing that we know what the  
20 relationship is between the reduction in proteinuria and  
21 the reduction in end-stage renal disease, dialysis,  
22 transplant, death, and a lot of other hard endpoints. And  
23 we haven't come even to the first step. Validating a new  
24 surrogate is like hitting an inside-the-park home run, and  
25 we haven't even gotten to first base yet. So, I think

1 we've got a long way to go here.

2 DR. BORER: Particularly in Cleveland where the  
3 stadium is now smaller than it used to be.

4 DR. NISSEN: But the team is good.

5 (Laughter.)

6 DR. BORER: Alan?

7 DR. HIRSCH: I probably don't know either. Not  
8 to disrespect my renal colleagues, I also would like my  
9 protein in my urine to go away with treatment anecdotally,  
10 but when it comes to data and approval, my problem with  
11 surrogates is that we've been burned too often as  
12 clinicians, whether it's left ventricular hypertrophy as a  
13 surrogate marker -- I can go on and on -- VPBs with  
14 dysrhythmic drugs. So, if I was going to use proteinuria  
15 as a marker, I need some specific clinical outcomes and  
16 some kind of a dose response where I know, like with blood  
17 pressure, these many millimeters down affects these many  
18 cardiovascular risks, this LDL change affects this clinical  
19 outcome. I need some better handle on the dose response, I  
20 think as you said Dr. Kopp.

21 DR. BORER: I'm going to vote no also. With  
22 Dr. Kopp, I thought that the proteinuria data were very  
23 compelling as supportive evidence with another trial with  
24 harder endpoints, but by itself, the issues that everybody  
25 has mentioned, the relation of the magnitude of the effect

1 to the outcome of interest to us just is too poorly known  
2 to allow us to accept as a surrogate at this point.

3 Bob?

4 DR. TEMPLE: Well, I was very struck by the  
5 observation that at least one dose of irbesartan was able  
6 to produce a dramatic decrease in proteinuria that  
7 obviously had nothing to do with anything anatomical at  
8 all. So, maybe the other dose did something anatomical I  
9 don't know. But that was impressive, I thought, that it  
10 could go away so quickly, and it certainly seems reason for  
11 pause.

12 DR. LIPICKY: Jeff, I think you said that IRMA  
13 supported IDNT, and now you say that proteinuria is not a  
14 surrogate. Can you explain how you came to those what I  
15 think are disparate decisions?

16 DR. BORER: Yes, I can. I don't think they're  
17 disparate at all.

18 IRMA I believe gives me some information about  
19 the pathophysiology of disease and convinces me that the  
20 drug has an impact that's positive on the pathophysiology  
21 of the disease. That was supportive of hard body count  
22 data from another trial. Absent the hard body count data  
23 from the other trial, I would not have been in favor of --

24 DR. LIPICKY: But the body count was 22 and 24.

25 DR. BORER: Well, in my judgment the data in

1 their totality, for all the reasons that I stated that are  
2 going to be on the record when you read it, I thought were  
3 sufficient.

4 DR. LIPICKY: I withdraw my question.

5 DR. FLEMING: If I could, I'd like to, even  
6 though I voted against it being a surrogate, defend that  
7 there's logic to what Jeff has said. When I argue it's not  
8 established to be a surrogate, my belief is we have not  
9 come close to establishing the scientific evidence to be  
10 confident that when you simply show an effect on  
11 proteinuria, that we know that it's of the duration,  
12 magnitude, and all the other things we have to understand  
13 to know that it's reliably going to predict an effect on  
14 clinical endpoints.

15 Nevertheless, there's still a level of  
16 plausibility of efficacy that you gain from such an  
17 insight. Even if you have a marker that's not an  
18 established surrogate, you understand natural history, and  
19 if you can impact that marker, it provides some level of  
20 sense of plausibility. So, if in fact you believed that  
21 the first trial was close enough or was quite close, then  
22 something that's not a surrogate, but establishes a level  
23 of plausibility, could tip you over. I don't know if  
24 that's where you were, but it's logically consistent you  
25 could have that opinion.

1 DR. BORER: You said it better than I could.

2 I think we've completed the questions, but Bob  
3 has another.

4 DR. TEMPLE: No. I just want to say one thing  
5 and it's not tooting my horn because they were written by  
6 someone else. I think this was a terrific set of  
7 questions, and I want to compliment Norm Stockbridge and  
8 Ray who did them. It led to what I think is one of the  
9 more fascinating discussions I ever remember at an advisory  
10 committee that brought out all kinds of stuff.

11 DR. LIPICKY: Just Norman. I had nothing to do  
12 with it.

13 DR. TEMPLE: Okay, even better.

14 (Laughter.)

15 DR. BORER: Okay. With those disclaimers  
16 having been made, we'll adjourn and meet again tomorrow  
17 morning.

18 (Whereupon, at 5:50 p.m., the committee was  
19 recessed, to reconvene at 8:30 a.m., Friday, January 18,  
20 2002.)

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