

1 abdominal pain severity, because data in the literature
2 suggesting that patients with more severe pain may be less
3 responsive. So, that is the stratification that we did do.

4 But the 12 mg dose with data I could show you,
5 there was no difference between mild -- we broke it into
6 tertiles, and there was no difference. For the 4 mg dose,
7 there seemed to be a difference with people with severe pain
8 less likely to respond.

9 DR. WOLFE: That was pain only, though.

10 DR. LEFKOWITZ: That was pain only.

11 DR. WOLFE: Because the pain is just so difficult
12 to quantify. Constipation, at least you can get some
13 quantification.

14 DR. LEFKOWITZ: If you want to go to ESG125.

15 [Slide.]

16 This is a slide I showed before, and I am not sure
17 that this fully answers your question, because we don't look
18 at patients with very severe pain, but again, this was a
19 small number of patients in the study who had stools 3.5 on
20 the scale with 3 being somewhat loose. These are sort of
21 the middle group, and half the population with the cutoff on
22 4.5. This was the data I showed you earlier.

23 I guess you might be interested in the people
24 further out on the scale, but we didn't break out the data
25 that way.

1 DR. WOLFE: Any statistical analysis of these
2 patients?

3 DR. LEFKOWITZ: In terms of?

4 DR. WOLFE: Any statistical difference in --

5 DR. LEFKOWITZ: I mean clearly between here and
6 here, they looked quite similar. We didn't run formal
7 statistics on this data.

8 DR. HANAUER: Other questions to the sponsor from
9 the committee?

10 [No response.]

11 DR. HANAUER: I want to handle a few questions
12 that were left over from the statistical group before we go
13 to the big picture questions that the Agency has asked the
14 committee.

15 Going back to the statistical assessment, and the
16 sponsor can address some of these questions, too, the first
17 issue is that the summary from Statistics said that there
18 was a significant treatment effect demonstrated in female
19 patients in Study 301, that was supported by the post-hoc
20 analysis in 351, but not replicated in 307.

21 What is the difference? Why was there no effect
22 seen in 307? A treatment effect was not demonstrated for
23 either dose in 307. I am asking you or the sponsor.

24 DR. WOLFE: No one knows. We can't give an
25 answer, we can only speculate, but I think I have two

1 explanations why -- I don't think 307 -- first of all, the
2 dose escalation I think just enhances the placebo response
3 because if one works, three is better, so you are just
4 actually help encourage those.

5 If you looked, they had a sharp rise, at least
6 some of the data they had a sharp rise in improvement as
7 they escalated, even placebo. So, I think that study right
8 there really may have hurt them.

9 DR. HANAUER: Along those lines, were the number
10 of tablets a day increased, or was the dose increased in
11 dummy tablets?

12 DR. LEFKOWITZ: The number of tablets were kept
13 constant, at two tablets twice a day. By study design, the
14 patients were not supposed to know when they were being dose
15 escalated. Clearly, the study coordinators knew because
16 they had to give them the correct drug supply.

17 We certainly suspect that the patients did know
18 that week before was the time of dose titration, however.

19 DR. HANAUER: You think they knew.

20 DR. LEFKOWITZ: Yes. That would be my
21 speculation, speculation.

22 DR. WOLFE: The other reason is that from 4 to 12,
23 regardless of the question of desensitization and
24 tachyphylaxis being, yes, less common with partial agonists,
25 it still does occur, and if you have a little bit of a drug

1 working, you up the dose at that point, you will not
2 probably have the effect that you would have by starting off
3 with a higher dose in the beginning.

4 So, it is all speculation, but again, I don't
5 think there is a very good dose response curve demonstrated
6 for this drug, and the doses may have actually, 4 and 12, as
7 far as -- we can't measure acid secretion. I mean we don't
8 have an objective parameter to measure here.

9 It makes it very difficult to really determine
10 what is the optimal dose. You are looking at symptoms only.
11 So, for that reason, 4 and 12 are going to be very similar
12 in regard to the response.

13 DR. LAINE: I was going to ask actually, the
14 sponsor, experts, or anybody else, the only trial that was
15 clearly positive, 301, was done completely in Europe. 351
16 was done in the United States and did not achieve the
17 primary endpoints, and 307 was done two-thirds in the United
18 States.

19 Certainly, in other GI diseases, we have dramatic
20 differences in responses between the U.S. and extra U.S.
21 populations. Do we have data on IBS and differences that
22 occur in different populations? This is again the only
23 study that was positive was the European study without U.S.
24 patients.

25 DR. LEFKOWITZ: As I showed earlier, what we

1 looked at were the demographics of the patients, the
2 baseline characteristics of the patients, and they were
3 almost --

4 DR. LAINE: That is not really the point. The
5 point is do we have -- we have lots of, as we talked about
6 at lunch, lots of peptic ulcer studies that showed marked
7 differences between healing rates in the United States and
8 Europe, H. pylori, I mean there is lots of different
9 precedents for that.

10 I am not really talking about your study, because
11 your study clearly did show a difference in response between
12 -- or it seems to me at least -- between European and non-
13 European, or European and U.S. studies.

14 What I am asking is are there other studies to
15 show similar differences in responses depending on different
16 countries? I mean there have been previous IBS studies
17 either the Glaxo's information or other studies that we have
18 had in the past.

19 DR. LEFKOWITZ: I can't comment on the other
20 studies. I would just submit that my interpretation of the
21 data is that the response rates in Europe and U.S. were
22 overall quite similar, 301 and 351, the results were quite
23 consistent between the two studies.

24 DR. LAINE: The only problem is 351 was really,
25 you know, was positive only after you had already seen the

1 results, so I think we have to take that with a grain of
2 salt or at least certainly not as a pivotal trial.

3 DR. LEFKOWITZ: I understand that, but what my
4 point is, however, is that the overall response rates, the
5 treatment differences in those two studies were actually
6 quite similar.

7 DR. HOUN: The Glaxo experience was U.S. only for
8 those pivotal trials.

9 DR. HANAUER: Other comments regarding that 307?
10 Did you want to say anything about 307?

11 DR. SURAWICZ: No. It is just that I don't think
12 the panel can answer why 307 wasn't successful. The company
13 would. I think they have done an excellent job in their
14 presentation and handling questions, and it is obvious that
15 the placebo rate is -- the response rate is so high there.
16 Why those things happened, I don't think we will ever know.

17 DR. HANAUER: The other question back from
18 Statistics was whether or not the effect, has the effect of
19 treatment on abdominal pain been adequately assessed, the
20 specific aspect of abdominal pain.

21 Are you comfortable with the way that that was
22 evaluated in these trials?

23 DR. LAINE: Are you asking how it was evaluated or
24 what the results were?

25 DR. HANAUER: That was one of Sonia's questions.

1 DR. LAINE: I am asking to kind of clarify, are
2 you saying do we think the scale that they used was
3 appropriate or inappropriate, or are you saying that since
4 it didn't achieve statistical significance, we don't think
5 they have documented that they have abdominal pain relief?

6 DR. CASTILLO: I think the Division wants to know
7 if it was adequately assessed.

8 DR. HANAUER: You mean is the instrument an
9 adequate assessment?

10 DR. LAINE: I am not sure that we are the ones to
11 say about the instrument. If the instrument is adequate,
12 then, their endpoint was not significant in their trials.
13 Their secondary analysis looked at that obviously, and gave
14 different views, but they had a lot more data points there
15 to show small differences being statistically significant.

16 So, I mean I would say that their primary
17 endpoint of pain, if it was an adequate instrument, did not
18 demonstrate abdominal pain relief, but on the other hand, I
19 can't comment on whether that scale is indeed the proper
20 instrument.

21 DR. TALARICO: The question was whether it was
22 adequately represented in the study population, and from the
23 result, is there any trend that indicates should that
24 population be expanded, that efficacy may be demonstrated.

25 The other question that we would like an answer,

1 is the disease the same in men and female, is there a
2 physiological -- as part of the IBS.

3 DR. LAINE: The men doesn't seem to matter anymore
4 because they have already changed their proposed indication
5 to female, so it seems it is really a --

6 DR. CASTILLO: I think the question is in the
7 overall picture of constipation-predominant IBS, pain is an
8 important clinical component of it, and has it been
9 adequately assessed in these trials. I think that was what
10 we were looking for.

11 DR. GALLO-TORRES: One is pain by whatever means
12 isolated by itself, even by a VAS. That is one way of
13 assessing pain alone. If one assesses pain as a component
14 of a global parameter, that is really the core of the
15 question, which one is more applicable and more useful, more
16 meaningful, which would of the two approaches, and has the
17 sponsor done the proper evaluation of pain.

18 DR. LAINE: Remember there was the one question
19 that we accepted in the previous alosetron submission. Does
20 somebody have that readily available, exactly what that
21 question asked by way of comparison? That was a global
22 question, if you remember, do you feel better. Did that
23 specifically say pain or was it generally, how do you feel?

24 DR. GALLO-TORRES: There is a question with the
25 alosetron included that were irritable bowel syndrome pain

1 and discomfort. That was a very meaningful type of
2 question.

3 DR. LAINE: It said irritable --

4 DR. GALLO-TORRES: Irritable bowel syndrome pain
5 and/or discomfort.

6 DR. LAINE: All I am asking I guess was that one
7 that we accepted last time, was that specifically pain --
8 certainly, the Rome criteria still requires pain or
9 discomfort as the primary reason for having a symptom in IBS
10 with the constipation being -- and the other bowel habits --
11 being contributory.

12 So, I would think you would still want to make
13 sure pain and discomfort it seems is still the number one
14 issue presumably in irritable bowel syndrome, although
15 patients certainly complain about all the other aspects of
16 bloating and alteration of bowel habits, as well.

17 DR. HANAUER: Dr. Camilleri and then Dr. Wolfe.

18 DR. CAMILLERI: I was just going to provide the
19 information, that the question in the other trial posed the
20 following question: Have you achieved adequate relief of
21 your pain or discomfort, and it pertains to the past week?

22 DR. HANAUER: Thank you. Dr. Wolfe.

23 DR. WOLFE: I wasn't here for the other one, but
24 these people don't come here with isolated pain, it's a
25 whole syndrome, and I think the pain question has been

1 looked at fairly carefully, but the overall quality of life
2 question, I am not sure if that has been answered.

3 That is my biggest question. The other thing,
4 too, when we see patients like this, some of these comments
5 bring back nightmares or daymares. These patients, I rarely
6 aim for a complete relief, so maybe the original questions
7 have not been realistic, and partial relief on a scale may
8 have been a better question to ask. What you do
9 retrospectively is a different question all together.

10 DR. LAINE: It seems to me that I guess the
11 question being asked, though, is if pain is indeed
12 important, their primary and secondary endpoint of pain did
13 not achieve significance except I guess in 301 with the
14 higher dose.

15 However, when they did the secondary analysis of
16 pain with the many data points, they did have significance,
17 so the question I guess is if they didn't achieve it in
18 their primary analysis of pain, is that important, is that
19 one of the things you are asking?

20 In other words, if they don't achieve it in pain
21 in two of the three studies.

22 DR. COHEN: I would just comment that when you
23 look at it as a secondary efficacy variable over the course
24 of the study, for one study 301, for 11 of the 12 weeks
25 there was less pain, to me, in terms of measurement of pain,

1 and there is a whole science of pain reduction, that was
2 clinically significant, as well as statistically
3 significant.

4 I think the question that you are raising, was
5 that enough to give the patient overall relief, and that is
6 reflected in the global relief. I think if you look at the
7 data both as a statistician and as a clinician, I think
8 there is clinical relief of the major components of IBS as I
9 presented it.

10 I think the question that you are asking is
11 whether or not that is enough of a relief, and I think that
12 is a very hard -- I don't know if anybody can answer that.

13 DR. HANAUER: Which brings us to the second
14 question up there, which is behind us, are the therapeutic
15 gains seen clinically significant, clinically meaningful.

16 DR. COHEN: I can answer that. I think that in a
17 disease or a syndrome where there is nothing out there,
18 there is no efficacious parameter, over the years in
19 practice we have gone through all of the drugs including
20 calcium channel antagonists, things that weren't even
21 mentioned on Dr. Wald's slide, and nothing has had proven
22 efficacy.

23 So, if you are looking at a margin of
24 effectiveness of an agent, and it does relieve pain, it
25 improves bowel function, I personally think it's clinically

1 meaningful, and the term that I used, I said it was a
2 moderately effective drug for the relief of the pain and the
3 constipation in this group of patients.

4 DR. LAINE: What I was going to raise, though, is
5 that methodologically, you would think you would first look
6 at your primary evaluation of pain, and when you looked at
7 that, you didn't show significance.

8 It was when you started looking at your secondary
9 evaluations, you did show significance -- excuse me -- you
10 showed it in one trial with 12 mg, I don't mean to diminish
11 that. Then, you started to show significance.

12 DR. HANAUER: Okay. But what you were asking
13 early on, is a 0.2 --

14 DR. LAINE: Right, 0.2 on a scale of 6.

15 DR. HANAUER: -- meaningful, not significant.

16 DR. LAINE: Or can a patient even discriminate
17 that.

18 DR. HANAUER: I think that is really the question
19 at hand at the moment that the Agency wants to know, is
20 whether the therapeutic gains -- we understand where they
21 were statistically significant -- now, is that 0.2 or
22 whatever percentage clinically meaningful.

23 Dr. Wald: We won't pay attention, but we will
24 listen.

25 DR. WALD: I think if we get away from the

1 statistics, that what you have is a big dilutional effect.
2 You have many patients who are getting better on the
3 placebo, and then you have other patients who are not
4 getting better either with placebo or the drug.

5 Then, you have about 10 percent of these patients
6 getting better and accounting for the difference, which is
7 only an average or a mean on those slides.

8 So, if you took the 10 percent and you took those
9 averages of 0.2 or 0.3, you could be dealing in those 10
10 percent with 2 or 3, not 0.2 or 0.3.

11 So, it seems to me intuitively that for those
12 patients who did experience relief beyond placebo, that
13 those are probably clinically significant changes.

14 DR. HANAUER: Do you want us to poll the panel on
15 these questions or no, you have got a sense on this aspect.
16 Okay. Dosage, we are going to come to I think in the main
17 questions. I think we are going to hit all of these in the
18 main questions.

19 What I would like to do is take a 10-minute break
20 now and then we will come back and go through the list of
21 the questions of the Agency. We will definitely reconvene
22 exactly at 3:00.

23 [Break.]

24 **Discussion and Questions**

25 DR. HANAUER: Setting a bit of the ground rules

1 for the questions, you have seen the questions, you should
2 all take out of the packet, so the committee has the
3 questions.

4 The ground rule that we have been asked to do is
5 to address the questions as they stand. Now, we understand
6 the sponsor, Novartis, has written another potential
7 indication up on the board, which we appreciate their
8 flexibility, but we are going to go back to what we were
9 asked to assess from the data that was provided at hand, and
10 then we can go back at the end of this and talk about
11 modifying the statement of indication.

12 Quite specifically, the statement is that Novartis
13 Pharmaceuticals Corporation has requested approval for
14 Zelmac (tegaserod) Tablets for the treatment of irritable
15 bowel syndrome in patients who identify abdominal
16 pain/discomfort and constipation as their predominant
17 symptoms. The sponsor recommends a dose of 6 mg po BID
18 within 30 minutes prior to a meal.

19 So, the first question that the committee has been
20 asked to ponder is:

21 1. Has efficacy been demonstrated in both men and
22 women with constipation-predominant IBS? If not, in which
23 gender was efficacy demonstrated?

24 I think let's just take the issue of men right now
25 as a simple point.

1 Any discussion on the issue of whether or not
2 efficacy has been demonstrated in men? Any discussion?

3 [No response.]

4 DR. HANAUER: We now go for a vote.

5 Has this been demonstrated to be effective in men?

6 Dr. Wolfe.

7 DR. WOLFE: No.

8 DR. HANAUER: Dr. Smith.

9 DR. SMITH: No.

10 DR. HANAUER: Dr. Richter.

11 DR. RICHTER: No.

12 DR. HANAUER: Dr. Buyalos.

13 DR. BUYALOS: No.

14 DR. HANAUER: Dr. Laine.

15 DR. LAINE: No.

16 DR. HANAUER: Dr. Ferry.

17 DR. FERRY: No.

18 DR. HANAUER: No.

19 DR. SURAWICZ: No. Men are different.

20 DR. WISON: No.

21 DR. HAMMES: No.

22 DR. HANAUER: Now for the tough parts. Okay. We
23 are going to limit this then to women for our discussion.

24 Has efficacy been demonstrated in women with
25 constipation-predominant IBS? Then, we will go back to

1 specifics.

2 DR. HAMMES: Yes.

3 DR. WISON: Yes, depending on our definition on
4 efficacy.

5 DR. SURAWICZ: Well, I wasn't here in November,
6 but I read the transcripts, and I understand that that drug
7 had an efficacy of 10 percent above placebo, and that's the
8 same here, so I think we have made that decision, and the
9 answer is yes.

10 DR. HANAUER: Yes.

11 DR. FERRY: I am going to vote yes, too.

12 DR. LAINE: No.

13 DR. BUYALOS: No.

14 DR. RICHTER: No.

15 DR. SMITH: Minimal, yes.

16 DR. WOLFE: Equivocally, yes.

17 DR. HANAUER: This is not a plurality here. It is
18 not necessarily democratic. This is an advisory committee,
19 so they take advice as to speaks loudest.

20 Now, the question is assuming yes, which of the
21 follow doses have demonstrated efficacy, and the options are
22 4 mg/day, 12 mg/day, or the titration?

23 Why don't we just discuss this point. Michael.

24 DR. WOLFE: The way it looks, the data looks, if I
25 want to say yes, and I did, 12 mg would be the dose.

1 DR. HANAUER: Dr. Smith.

2 DR. SMITH: 12 mg.

3 DR. RICHTER: I go with 12 mg.

4 DR. BUYALOS: 12 mg.

5 DR. HANAUER: You can't say anything. You don't
6 think it's effective, but I will let you comment, but not
7 vote.

8 DR. LAINE: I think there is minimal dose
9 response, but certainly in some studies, only 12 mg did make
10 the primary endpoint, so 12 mg.

11 DR. FERRY: I would say 12 mg is the dose to go
12 with. I think that was the closest, best response.

13 DR. HAMMES: I actually thought that both were
14 fairly comparable, but I think that since we don't see any
15 significant dose-related toxicity, I would say it is 4 to
16 12.

17 DR. SURAWICZ: I favor that, as well. I mean why
18 use a higher dose if some people, even though it's a small
19 number, would have response at a smaller dose, and then as a
20 clinician, you never like to use your whole regimen at the
21 beginning. You always like to start with something, and if
22 it doesn't work, you can increase the dose and see if that
23 works. So, as a clinician, I would be much more comfortable
24 with Option No. 3, titrated dose regimen from 4 to 12.

25 DR. WISON: I would say that 4 in the initial dose

1 trials was an effective dose, and subsequently in the
2 others, was not different, so I would go with 4.

3 DR. HAMMES: If our first duty is to do no harm,
4 and given the great placebo effect, I would say start with
5 1, but I would go with the titrated regimen, start with 4.
6 Why use 12 if 4 works.

7 DR. HANAUER: Do you guys want to follow up any of
8 these?

9 DR. WOLFE: Can we discuss this?

10 DR. HANAUER: Sure. Now you say this.

11 DR. WOLFE: I am not sure if I agree with that. I
12 understand the point, starting this thing 4 versus 12, but
13 there are some suggestions that titrating may not work, may
14 actually cause more problems.

15 Why not say 12 for a short period of time and then
16 if you want to try, some studies in the future, so you
17 maintain your patients at 4, certain patients that need
18 maintenance therapy, go down, but if you wanted to use the
19 analogy of patients with reflux disease, we don't use a
20 lower dose of PPI and then go to a higher one. We start
21 with the dose of PPI and then see if we can sometimes go to
22 a lower one.

23 DR. HANAUER: Let me comment for a moment. We are
24 not describing clinical practice here and what we should
25 really be doing as an individual patient. What we are doing

1 is making recommendations for dosing, labeling for the
2 Agency, and how you use the drug will be reflective on your
3 experience and everything else.

4 DR. WOLFE: Then, I will go back to what the data
5 did show. The data did show that titration to a higher dose
6 was the weakest response of all, so I would really question
7 whether we should really use titration as our parameter for
8 dosing.

9 DR. LAINE: I mean I hate to be data driven on
10 this committee, but, you know, if we look at their results,
11 I mean the places where they did achieve response in 301
12 with relief in abdominal pain was the higher dose, and not
13 the lower dose.

14 If we look at their non-pivotal 351 in retrospect,
15 again, it was 12 mg. So, it would strike me, although I
16 agree there is not much of a dose response, the one they
17 have shown more likely to work is 12.

18 In addition, the only reason you use the low dose
19 first is if you have concerns about cost, which we are not
20 discussing, or safety, which I don't think we have seen any
21 concerns about at the higher dose, or side effects, which I
22 don't think we have seen any dose-related effects.

23 So, although typically, you know, we are taught to
24 use the lowest dose first, if there is no safety, cost, or
25 tolerability issue, I am not sure there really is any point

1 DR. LEFKOWITZ: For the abdominal pain, it
2 significantly improved; for the SGA of relief, it did not.

3 DR. HANAUER: There is a little bit of confusion
4 from everyone's standpoint of who really does get to vote,
5 and the guests don't get to vote. You can vote, but it is
6 not counted. So, I am going to ask Tom to recap the vote on
7 those first things, so we know.

8 Do you want to go through them?

9 MR. PEREZ: On Vote No. 1 regarding efficacy in
10 men, it was unanimous. Efficacy in women, there were two
11 no's, the rest were yes. What doses demonstrated efficacy:
12 4, we had a vote of 1; 12, we had a vote of 4; titrate, 3.

13 DR. HOUN: Let's just identify the guests are our
14 two OB-GYN experts.

15 DR. HANAUER: Dr. Smith and Dr. Buyalos.

16 DR. HOUN: I guess I want to clarify the vote on
17 female. I had thought that initially, there were three no
18 votes by Dr. Buyalos, Dr. Laine, and Richter. So, Dr.
19 Buyalos' vote is not official.

20 DR. HANAUER: We won't confuse you anymore. We
21 won't let them vote.

22 Next question. Comment -- and we will have
23 discussion before we have a vote -- but comment on the
24 following findings of the carcinogenicity studies.

25 First, mucosal hyperplasia and adenocarcinoma of

1 What I would like is the two OB-GYN consultants to
2 comment first and then we will find out whether there is
3 more of an opinion from the panel.

4 DR. BUYALOS: First off, ovarian cysts is a very
5 generic term. It really doesn't mean anything to an OB-GYN
6 per se. In the course of follicular genesis, cyst
7 formations form, so there are a number of different studies
8 in different mice and rat species, if you expose them to
9 things such as androgens early in their gestation that allow
10 these multiple nonspecific cystic structures on the ovary.

11 So, I don't find this troubling in the slightest.

12 DR. SMITH: I concur. I believe that it is a true
13 finding in the female Wistar rats, but I would never want to
14 equate the physiology of a female Wistar rat to human
15 females, and I think that this is just a documented
16 incidental finding with no clinical relevance, especially in
17 light of the human data.

18 DR. HANAUER: Was the sponsor's spin on the
19 ovarian cyst team in the clinical trial also adequate for
20 you?

21 DR. SMITH: Absolutely.

22 DR. BUYALOS: Yes, it was.

23 DR. HANAUER: Is there any dissent or concern from
24 the other panel members regarding the animal studies or the
25 human studies with ovarian cysts?

1 making light of the, quote "diarrhea," but diarrhea is a
2 huge clinical problem.

3 DR. WOLFE: As long as it goes away, as long as it
4 stops is what I am saying, it stops right away.

5 DR. HANAUER: Right. What you are saying is the
6 diarrhea that you have heard about related to the clinical
7 trials is not a severe diarrhea that you are concerned
8 about.

9 DR. WOLFE: Right, yes.

10 DR. HANAUER: Joel.

11 DR. RICHTER: I would agree, Steve. I think it
12 tends to be a mild problem. It looks like only about 2 to 5
13 percent of patients are discontinuing the studies because of
14 it, and apparently it looks like if you stop the medication,
15 the diarrhea goes away.

16 DR. HANAUER: It looked like that alosetron, too,
17 as far as the patient until marketing when we have seen some
18 serious events.

19 Do you feel that what you have heard requires any
20 postmarketing surveillance regarding the severity of
21 diarrhea?

22 DR. LAINE: Could I just ask, Steve, were there
23 any hospitalizations for diarrhea among these
24 discontinuations?

25 DR. LEFKOWITZ: There were no serious adverse

1 events reported for diarrhea. There was also no electrolyte
2 problems that the patients ran into due to the diarrhea.

3 DR. LAINE: So, no significant dehydration
4 problem?

5 DR. LEFKOWITZ: That is correct.

6 DR. HANAUER: By the way, I am not trying to imply
7 anything. I am just trying to get everything out early, so
8 that we don't have to go through this, as they say, do this
9 again next year.

10 DR. FERRY: Can I ask one more? Were there
11 patients in the study you had diarrhea that it didn't
12 resolve, or the ones that didn't drop out, what happened to
13 the diarrhea?

14 DR. LEFKOWITZ: Most of the patients who had
15 diarrhea in fact stayed in the study. The dropout rate was
16 1.6 percent for the tegaserod group, the incidence being 12
17 percent. Most patients either stopped the drug and then the
18 drug was reintroduced and they were able to continue in the
19 study.

20 DR. HANAUER: I just want to hear this again. No
21 hospitalizations for diarrhea, no treatment for dehydration?

22 DR. LEFKOWITZ: Certainly no electrolyte
23 abnormalities reported to us, and as far as we know, no
24 clear-ups of the dehydration.

25 DR. HANAUER: Thank you.

1 DR. FERRY: I was just going to say that is
2 important, I mean if we are talking about labeling later on,
3 with what has happened to alosetron, if we want to be
4 careful with this, it sounds like most of the patients in
5 the study did stop the drug temporarily, it wasn't like they
6 continued it and the diarrhea just went away, so that may be
7 a consideration that we should address.

8 DR. LEFKOWITZ: Yes, 30 percent of the patients
9 who had diarrhea within the first two weeks missed at least
10 one dose of the drug. So, in fact, most patients were able
11 to continue in the study, and the diarrhea would resolve.

12 DR. HANAUER: From the Agency, did we address that
13 adequately for you guys? Yes? Okay.

14 The next issue relates to the lower abdominal pain
15 and the laparotomy in a greater proportion of patients
16 receiving Zelmac.

17 Any comments from the committee regarding this
18 issue? Again, from the OB-GYNees, this is not troublesome
19 to you? Anyone find a problem or a comment?

20 [No response.]

21 DR. HANAUER: Agency, Hugo, is there a concern?

22 DR. GALLO-TORRES: Some lingering concern about
23 that in my mind. How often do you see surgical
24 interventions in patients with IBS?

25 DR. HANAUER: That is difficult, because you have

1 asked the OB-GYNees, you are going to see the numerator, if
2 you ask us, we see the denominator.

3 DR. SMITH: We are going to see a different
4 population, but the general rule of thumb in OB-GYN is that
5 of women who are presenting with abdominal and pelvic pain,
6 abdominal pelvic pain chronic in recurrence, 40 percent is
7 due to pelvic disease, 40 percent is gastrointestinal
8 disorder, such as irritable bowel or chronic constipation.
9 A tremendous number of these ladies go through laparoscopic
10 procedures to diagnose it, only to find large, distended
11 intestines and colon. So, the diagnosis of constipation is
12 made with a perfectly normal pelvis.

13 Then, there is a bunch of other less common
14 etiologies for the chronic pelvic pain that can range from
15 urinary tract to pelvic floor triggers and musculoskeletal
16 problems, but 40 percent of all abdominal pelvic pain that
17 we see as OB-GYNs is actually constipation and irritable
18 bowel.

19 DR. GALLO-TORRES: What proportion, more or less,
20 of those patients have appendicitis?

21 DR. SMITH: A small percentage, because that would
22 be short-term pain. Very few patient really are presenting
23 with chronic appendicitis, so, you know, the one lady who
24 came here had a background of chronic pain, but what was
25 going on is that she had an acute appendicitis at that time,

1 unrelated to medicine. It was just an incidental occurrence
2 during the study period, and that was also -- was that the
3 13-year-old? I am not sure.

4 DR. GALLO-TORRES: And a final question related to
5 this. How many of those patients have adhesions as a
6 previous history?

7 DR. SMITH: How many of those patients have
8 adhesions?

9 DR. GALLO-TORRES: Yes, adhesions.

10 DR. SMITH: I think a fair number of the 40
11 percent who have pelvic pathology are going to be having
12 abdominal pelvic adhesions as an explanation for the chronic
13 pain, but the flip side is that an awful lot of patients
14 with adhesive disease have absolutely no pain symptoms at
15 all.

16 So, it is not a tight correlation at all between
17 the presence and absence of adhesive disease and the
18 presence and absence of chronic abdominal pelvic complaints,
19 but my impression in reviewing the case reports is that I
20 have no suspicion of a relationship between the medication
21 and adhesive disease or a propensity towards having a
22 laparotomy, and think that in some cases, personally, that
23 it was treatment failure and breaking through of the
24 medication and worsening of the irritable bowel syndrome
25 that was the actual stimulus for the surgical intervention.

1 DR. BUYALOS: I would agree with that, and in
2 fact, if you look at the algorithm for pelvic pain in
3 gynecology, we have typically treated with medical
4 therapies, oral contraceptives or non-steroidal,
5 inflammatory type products, but as part of that algorithm, a
6 diagnostic laparoscopy is frequently employed.

7 We are seeing a different population than
8 gastroenterologists obviously, and the second thing is the
9 histories are very muddy on the case reports that they have,
10 but a substantial proportion of them were having prior one
11 to two years beforehand, so I don't find it in the least
12 concerning from that perspective.

13 DR. HANAUER: Thank you. So, I think you have a
14 unanimous no conflict from the committee on this.

15 We are now going to some of the critical
16 questions, which is, on the basis of your benefit-risk
17 evaluation, which is going to be key word for tomorrow, do
18 you recommend that Zelmac be approved for the indication
19 requested by the sponsor, that I stated above, which is
20 approval for Zelmac tablets for the treatment of irritable
21 bowel syndrome in patients who identify abdominal
22 pain/discomfort and constipation as their predominant
23 symptoms?

24 For that indication, do you recommend approval?

25 DR. WOLFE: Is there a length of time attached to

1 that?

2 DR. HANAUER: What you saw is what you get. You
3 don't have to answer now. That's a legitimate question, and
4 there is no length of time assessed on that.

5 DR. WOLFE: I mean at least minimally, it should
6 add in there short term. At this point, I think that is all
7 we have seen. It doesn't say short term from what you just
8 read.

9 DR. HANAUER: By "short term," do you mean three
10 months, 12 weeks?

11 DR. WOLFE: That is what I just asked, but at
12 least it should say short term. We will define what short
13 terms means later on. I don't think it should be
14 indefinite.

15 DR. HANAUER: This is a comment phase. You are
16 not voting on it.

17 DR. WOLFE: I think it should be short term, and I
18 would say 4 to 6 weeks right now is all I would say, because
19 I think the benefit -- I didn't see the benefit really
20 getting that much greater as time went on.

21 DR. LAINE: I would say you have to go with what
22 the studies did, and although I didn't vote for it, I mean
23 if you are going to approve it, you are approving it on the
24 basis of the studies, so it seems to me you have to say 12
25 weeks, so you can't say more, you can't say less, it's 12

1 weeks.

2 DR. HANAUER: Do you have to say anything?

3 DR. HOUN: Or are you recommending other studies,
4 the short-term study?

5 DR. HANAUER: We will come to that.

6 DR. LAINE: My view would be you would say that
7 because I think nowadays you are trying to be, you know, you
8 get the indication based on what studies you did, not on
9 what we kind of assume. So I would probably -- I don't know
10 that you want to approve -- if you don't say anything, then,
11 that means you can use it for years and years, which people
12 are going to do anyway, but I think it would be reasonable
13 now, before further studies are done, just to go with what
14 their trials were, so I would say 12 weeks.

15 DR. WOLFE: Is that what we are doing? We just
16 took men out, and the study wasn't done to look at women
17 only, it was done to look at people, and we just took men
18 out and made it for women only.

19 So, I think we have the right to look at both the
20 gender, as well as the length of time.

21 DR. HANAUER: Absolutely. You are here to make
22 recommendations.

23 Other comments on this issue? Joanne.

24 DR. WISON: We are somewhat hindered in making
25 recommendations of duration, because if we knew that

1 symptoms recurred immediately upon discontinuing the
2 medication, then, we could make a recommendation for longer
3 periods up to 12 weeks, but as it stands now, people got
4 maximal response in shorter periods of time.

5 So, therefore, I would go with your recommendation
6 for a shorter duration.

7 DR. HANAUER: So, do you have a recommendation
8 regarding -- Dr. Wolfe said 4 to 6 weeks based on --

9 DR. WISON: Looking at some of the data, looking
10 at what the response has maxed out, and it was somewhere
11 like 4 to 6 weeks.

12 DR. HANAUER: Dr. Wolfe.

13 I will point out as a clinician, as well as a
14 chairman here, once you put a duration on it, you are going
15 to get all sorts of hassles from third-party payers saying
16 that you have over-extended your duration.

17 Now, that is not the Agency's concern, but that's
18 a clinician's concern.

19 DR. WOLFE: But the thing is where do you stop?
20 You say, well, for 12 weeks, let's go on for 12 years.

21 DR. HANAUER: The point is do you want to really
22 put in a term limit, do you want to have term limits on this
23 indication?

24 DR. WOLFE: There is precedence to that. I mean
25 this has been done for other diseases, as well. I mean

1 unfortunately, it was done for reflux disease, because it
2 was treated like peptic ulcer for years and years, but with
3 the proper studies, we realized that longer term treatment
4 was necessary.

5 I don't think we have shown that here yet. We
6 haven't seen trials beyond that, and the longer it is
7 treated, 12 week starts to sound like more of a chronic use
8 to me. I don't know. I arbitrarily said 4 to 6 weeks, it
9 was arbitrary.

10 DR. HANAUER: I would just again in the discussion
11 phase argue against that. To me, what we have heard the
12 likely use is going to be intermittent by the experts, but
13 if you put a 4 to 6 week term on it, your third parties are
14 going to stop the treatment if you decide to reinitiate it
15 or give it longer.

16 DR. RICHTER: Steve, I would go with what Loren
17 was suggesting. Both he and I voted no on this, but based
18 on the data, if you were talking about a recommendation --

19 DR. HANAUER: Well, you voted no, that it wasn't
20 effective. You didn't say to approve it.

21 DR. RICHTER: I would give the length of duration
22 of this as up to 12 weeks, because that is what your data is
23 showing, and that allows you both options. You could use it
24 for a shorter period of time if that's what the patient is
25 telling you they only need it to, and it also protects you

1 from the third-party payers who don't want you necessarily
2 to extend it indefinitely, and we don't have any definite
3 date on this medication at this point in time.

4 DR. WOLFE: Once again, is that our job to worry
5 about whether third-party payers are paying or not?

6 DR. HANAUER: Your job isn't, but I am being --

7 DR. WOLFE: I understand, you are being a
8 clinician, too. We have the same trouble, getting all these
9 letters from managed care.

10 I am thinking of other PI's that say effective
11 therapy has not been demonstrated beyond a certain period of
12 time. Have we demonstrated an effect beyond 4 to 6 weeks?

13 DR. HANAUER: Dr. Smith.

14 DR. SMITH: Well, I disagree that the common
15 usage, speculation, of course, is going to be short and
16 intermittent term. Patients call into the office. They
17 will get a prescription by telephone, and they will refill
18 it by auxiliary staff in the office.

19 If what happens in the primary care physician's
20 office is anywhere similar to what happens in an OB-GYN's
21 office, who will be prescribing this just as readily, one,
22 the physicians will not have read the medical literature,
23 they will go by whatever is being in service by the
24 representatives from the company, and I would vote very
25 strongly that it's approved for short-term treatment, and

1 you don't have to specify short term, and that the efficacy
2 with prolonged treatment and recurrent treatment is not
3 proven, and it is up to the company to establish the
4 efficacy, as Dr. Laine said, with alternate forms of use, to
5 say that it is okay to use it three times every two years or
6 for 16 consecutive months, there is no proof, and I think
7 that the Agency has a responsibility to protect the public
8 from misinterpretation or embellishment of the true data.

9 The data itself is relatively weak, to begin with.

10 DR. FERRY: I am not too much in favor of limiting
11 a time period. I think that complicates things for a lot of
12 reasons, and I understand the concern about not really
13 knowing long-term use, but this is a -- I mean it appears to
14 be a pretty safe drug.

15 My guess is patients are going to want to use
16 this, the ones that get some benefit, and I sort of hate to
17 see it constrained that it only be used for three months. I
18 do think there is some real merit in doing some follow-up
19 studies to find out the true use long term, but I am not in
20 favor of setting a time limit on it.

21 DR. HANAUER: Other comments regarding this? Yes,
22 Dick.

23 DR. HAMMES: To put on my consumer's
24 representative hat here, by all accounts, this is a chronic
25 disease by definition, I guess. We are looking back 12

1 months to get them enrolled in it.

2 We have evidence that it is effective out to 12
3 weeks. We don't really know what happens beyond that, but
4 we do have safety data out a year or more, I believe, and it
5 is a very safe drug. So, I don't think we need to put any
6 limit on it. We can state that it has been shown to be
7 effective out to 12 weeks, but I don't think we need to
8 limit it.

9 DR. WOLFE: I really disagree with that. I think
10 the most you can say right now is 12 weeks. Whether you can
11 go beyond that, studies have to be done to show efficacy
12 beyond that time period.

13 This is again, and I hate to use the analogy of
14 other disorders, but we have the acute phase treatment and
15 maintenance phase treatment, and this is a chronic disorder
16 which is different from other chronic disorders, that this
17 waxes and wanes much more so than other disorders that are
18 chronic, and the short-term treatment may be effective in
19 certain individuals, and they get treated pulse by pulse
20 therapy instead of by chronic therapy, maintenance therapy.

21 DR. HANAUER: Joel.

22 DR. RICHTER: I just want to reemphasize what Mike
23 says. I mean I don't see how you can extend efficacy data
24 any longer than the study is. You can say this medication
25 is safe for up to a year, but there is no placebo-controlled

1 efficacy data past the data that we have for 12 weeks, and I
2 don't think you can make a recommendation past 12 weeks.

3 DR. HANAUER: We have time for labeling
4 modifications, but the first question is, "On the basis of
5 the benefit-risk, do you recommend that Zelmac be approved
6 for the treatment of irritable bowel syndrome in patients
7 who identify abdominal pain/discomfort and constipation as
8 their predominant symptoms?"

9 Dr. Wolfe.

10 DR. WOLFE: Yes.

11 DR. HANAUER: No, you don't. You want it in
12 females.

13 DR. WOLFE: Yes.

14 DR. RICHTER: No.

15 DR. HANAUER: Dr. Laine.

16 DR. LAINE: No.

17 DR. FERRY: Well, if we throw females in, yes. I
18 wouldn't do it this way.

19 DR. HANAUER: So, do it this way, and then you can
20 modify it.

21 DR. FERRY: So, it's no.

22 DR. SURAWICZ: I think I am missing what the
23 controversy is here.

24 DR. HANAUER: Well, the controversy is the
25 semantics of the labeling as is written up there. There is

1 other subtleties --

2 DR. WOLFE: If it's all people, I would think it
3 was no.

4 DR. HANAUER: Would you agree with the labeling of
5 Zelmac Tablets for the treatment of irritable bowel syndrome
6 in patients who identify abdominal pain/discomfort and
7 constipation as their predominant symptoms?

8 DR. SURAWICZ: Well, we have already talked about
9 its lack of efficacy in men, so is that -- are we rehashing
10 this again?

11 DR. HANAUER: No, we are voting.

12 DR. SURAWICZ: We are voting to approve or not
13 approve? I vote to approve.

14 DR. WISON: I vote no.

15 DR. HANAUER: No.

16 DR. WOLFE: Steve, I will have to change my vote
17 because I thought we were talking about women only.

18 DR. HANAUER: That is why I interrupted you.

19 DR. WOLFE: I say no.

20 DR. HANAUER: Okay.

21 DR. SURAWICZ: But we already talked about that.

22 DR. HANAUER: Yes, but now this is a vote.

23 DR. SURAWICZ: But we voted before.

24 DR. HANAUER: No, you voted whether you thought it
25 was effective.

1 DR. SURAWICZ: And we were unanimous that it
2 wasn't effective in men.

3 DR. HANAUER: Right, but we are sticking with that
4 label, because we were asked to stick to it. Now, you can
5 modify it if you would like.

6 DR. SURAWICZ: Great. Let's modify it.

7 DR. HANAUER: How would you like to modify it, Dr.
8 Surawicz?

9 DR. SURAWICZ: For use in women.

10 DR. HANAUER: Any other comments on the labeling
11 modification?

12 DR. WOLFE: Again, I think we have to come up with
13 a time limit, and maximally 12 except things say short term
14 in parentheses, as a compromise, 6 to 12 weeks.

15 DR. LAINE: I like up to 12, the way Joel said it,
16 even if I voted no.

17 DR. HANAUER: Any other comments regarding the
18 labeling before we come back to some of these individual
19 amendments? I particularly have one, and that is, I am
20 uncomfortable with the discussion of with the labeling that
21 says, "For treatment of irritable bowel syndrome in patients
22 who identify abdominal pain/discomfort."

23 My view is that the labeling should read, "For the
24 treatment of abdominal pain and constipation in patients
25 with irritable bowel syndrome." To me, that is a more

1 sensible labeling because you are treating symptoms and it
2 is not treating a long-term disease.

3 That is what we have looked at, that is what the
4 sponsor looked at.

5 DR. WOLFE: You may avoid, by doing what you are
6 saying, you may actually avoid people just saying, well,
7 here is another new drug, and we just go ahead and use it
8 for IBS, and not pay attention that there is a difference of
9 IBS.

10 DR. HANAUER: That is why I said it that way.

11 DR. WOLFE: I think you are right. It's
12 commendable.

13 DR. SURAWICZ: The only concern I have with that
14 is that if people don't read the entire sentence, and they
15 are treating any abdominal pain and constipation with this
16 drug, then, it is going to be a disaster.

17 DR. WOLFE: I don't know if it's going to be a
18 disaster or not.

19 DR. SURAWICZ: Well, yeah, because you are going
20 to be treating colon cancer and bowel obstruction, and all
21 kinds of stuff that causes abdominal pain.

22 DR. HANAUER: My approach also separates it from
23 the other drug, which is the treatment of irritable bowel
24 syndrome in patients with diarrhea-predominant. Here, you
25 know, IBS is IBS, whatever. I think that you are really

1 treating the symptoms of abdominal pain and constipation in
2 patients with irritable bowel rather than treating irritable
3 bowel syndrome in general.

4 DR. BUYALOS: Steve, is this a common phenomenon?
5 What other chronic condition is a medication approved, which
6 is gender specific? I am not familiar with that.

7 DR. HANAUER: Birth control.

8 DR. BUYALOS: I am talking about a chronic
9 condition which affects both sexes.

10 DR. HANAUER: According to the sponsors and
11 others, there is a gender difference in the affectation, in
12 the incidence. As a matter of fact, alosetron, which is the
13 other drug that was approved for diarrhea-predominant, was
14 also only effective in women.

15 DR. BUYALOS: Maybe that was a power phenomenon
16 also with the number of subjects in the study.

17 DR. HANAUER: Well, women have power, but that
18 didn't seem to be the issue seriously.

19 The next question is what labeling recommendations
20 -- we are in the process of addressing this, and I guess we
21 should take different aspects of it. I presume everyone on
22 the panel -- and I don't mean to vote for them -- agrees
23 that this should be limited to women, right? So, the
24 indication should have females in it. Any dissent regarding
25 that?

1 [No response.]

2 DR. HANAUER: Unanimous that the labeling should
3 discuss women.

4 I will just take them in order that they were
5 brought up. The second is the term limits. Do you want to
6 make a statement of proposal? Was your proposal short-term
7 treatment?

8 DR. WOLFE: Short term use. It should say short
9 term and then in parentheses take a week number. Again,
10 there is going to be some arguments here, but I agree with
11 Loren and with Joel, that it should really say up to 12
12 weeks, but looking at the data, I didn't see much effect
13 over 6 weeks, but I don't have any objection to 12 weeks.

14 DR. HANAUER: Well, make a proposal then.

15 DR. WOLFE: Short term parentheses up to 12 weeks.

16 DR. LAINE: I agree.

17 DR. HANAUER: Loren has agreed already. George,
18 comments?

19 DR. FERRY: I am still wondering what -- what does
20 that mean actually? That means that a doctor prescribing
21 this cannot -- I mean should not refill it after three --

22 DR. LAINE: No, because we don't set clinical
23 practice. All it means is that like a representative can't
24 perhaps go to the doctor and tell them that they should use
25 it beyond 12 weeks.

1 DR. FERRY: How will it read? How does this
2 translate into what would actually be written down? You
3 should stop this drug at 3 months, you should not use it
4 longer than 3 months?

5 DR. RICHTER: It would be no different than -- I
6 just cannot conceive of giving an indication for a drug
7 longer than you have the efficacy data and the study, and if
8 you want to say, well, the issues are chronic disease, this
9 is no more of a chronic disease than reflux disease. So,
10 when the PPI's come out of the H2 blockers, we gave those
11 drugs for 3 months, then, we would stop those, and then when
12 the patient's symptoms relapsed, we would start them back
13 until we had the maintenance data from the companies, and
14 then we do maintenance therapy now.

15 DR. WOLFE: We actually started using it long term
16 before that. We had studies in the literature showing long-
17 term effects, but here we don't have any studies, and we
18 have nothing in the literature suggesting this drug works
19 longer.

20 Again, what people do in practice is their
21 business, but we don't have data beyond that.

22 DR. HANAUER: Other comments? Yes, Dick.

23 DR. HAMMES: I still think by putting a limit on
24 it, clearly, you are going to be making this unavailable via
25 third-party payers, HMOs, or what have you, for people that

1 need it after 3 months, and I don't think there is any data
2 to suggest that it was not effective after 3 months, and I
3 really don't see any kind of data that indicates that we
4 should be proactive and put that kind of limit on it,
5 considering the effect that it is going to have on people
6 that may need it.

7 DR. HANAUER: Of the voting members, how many feel
8 -- just raise your hand if you feel there should be a short
9 term up to 12 week information on it?

10 [Show of hands.] Six.

11 DR. HANAUER: Opposed to that?

12 [Show of hands.] Two.

13 DR. HANAUER: Two. And the opposition states no
14 limit, no term limit, or you want to make a proposal or just
15 a comment?

16 DR. HAMMES: I don't think it needs to be
17 mentioned in the labeling.

18 DR. HANAUER: Timing need to be mentioned,
19 Christina?

20 DR. SURAWICZ: No.

21 DR. HANAUER: The third aspect of the labeling was
22 my notion of a label for the short-term treatment of
23 abdominal pain/discomfort and constipation secondary to
24 irritable bowel syndrome.

25 Additional comments regarding that?

1 DR. LAINE: Could we have the alosetron label read
2 to us perhaps? In other words, how was it written in terms
3 of diarrhea-predominant? I mean we could perhaps use that
4 as a precedent.

5 DR. HANAUER: I don't need if you need a precedent
6 or a fix.

7 DR. WOLFE: Steve, can you say constipation,
8 abdominal pain type irritable bowel syndrome, because
9 secondary to is -- associated with --

10 DR. HANAUER: I don't want to say type because I
11 don't think that they have shown that it is really effective
12 in -- that they can effectively type it is the problem.

13 DR. WOLFE: It is important, though, they are
14 going to start using it in people who have an obstruction,
15 an obstructing lesion of some sort without really --

16 DR. HANAUER: Contributed to irritable bowel
17 syndrome. You don't have to accept it, you can oppose it.

18 DR. WOLFE: I like the idea, but I think we need
19 some careful terminology here.

20 DR. HANAUER: So, the Agency will think through
21 that terminology of how you want to modify it. I think you
22 get a sense that there are different ways of saying this
23 that may impact upon the usage and miss-usage.

24 Aside from the short term that Dr. Wolfe has
25 already imposed, are there any other labeling

1 recommendations to reduce the potential risks of Zelmac, the
2 potential risks being diarrhea, right? Is it necessary to
3 black box diarrhea?

4 DR. WOLFE: List that as a side effect.

5 DR. HANAUER: As a side effect or a
6 contraindication?

7 DR. WOLFE: Well, it's a contraindication and side
8 effect.

9 DR. LAINE: I think it would be reasonable to,
10 because of the constipation issue, with alosetron to be
11 reasonable, not to black box it, but just to mention that
12 patients with predominant diarrhea or with -- you know, we
13 have to figure out the wording -- but who have diarrhea a
14 significant portion of the time should not receive this
15 medication, or something along those lines perhaps, at least
16 now until we get further information.

17 DR. HANAUER: Or that diarrhea is the most common
18 side effect. As a precaution? Tom wants to know. You guys
19 can figure that one out, that is pretty straightforward.

20 Now, I think these are the really important
21 aspects now. Dr. Houn, do you still care if operations are
22 necessary, what proportion is acceptable? The committee
23 really doesn't predict that that is going to be a problem.

24 DR. HOUN: Do you think there should be
25 surveillance on that?

1 DR. HANAUER: Does the committee think that there
2 should be surveillance regarding specifically the risks for
3 operations in patients, exploratory surgery?

4 DR. WOLFE: Any question that came up should be
5 watched carefully as far as I am concerned.

6 DR. HANAUER: Okay. If you should watch it, how
7 should they watch it? Does this require a case controlled
8 study? I think you heard from the OB-GYNees, and we know in
9 our practice, that oftentimes women with abdominal pain
10 associated with irritable bowel or whatever end up going to
11 laparoscopy as a diagnostic maneuver, and if they are going
12 to separate this as an issue of the background population of
13 this group of people, is there a way that they should do
14 that?

15 DR. WOLFE: There are postmarketing surveillance
16 studies to do postmarketing surveillance.

17 DR. HANAUER: What study?

18 DR. WOLFE: Long term on patients on this drug
19 open label. There are several studies that I could see
20 being done in the future, and that is one of them, do an
21 open label study, follow patients out, you know, follow
22 patients who have been taking it out for a certain period of
23 time.

24 DR. HANAUER: How would you ascertain then if
25 whatever proportion of patients go through surgery is an

1 increased risk? These are the kind of things that they want
2 to know, right? Aren't I getting to your points here?

3 DR. HOUN: Appropriate control group.

4 DR. HANAUER: What would be an appropriate
5 control?

6 DR. WOLFE: People treated by other means, people
7 treated with fiber only, people treated "in traditional
8 ways." It can't be a double-blind, obviously, it can't be
9 double-blind. It has to be a surveillance study of some
10 sort in which people are relying on reports or else relying
11 on -- I don't know.

12 DR. RICHTER: I think you are going to have to do
13 some maintenance studies with this medication versus
14 placebo, probably with the same study design that we use in
15 ulcer disease or GERD. Get a group of people that have had
16 a good response to the medication, and then at that point in
17 time, over a year's period, randomize them to either
18 maintenance medication or placebo unknown, and follow that
19 group out for efficacy over a year, and also look at some of
20 these other side effects because based on what we know, if
21 you are going to use the weaker endpoint of some relief, you
22 are going to have 40 or 50 percent of your patients staying
23 in the study on placebo.

24 That will give you a pretty good idea then, over a
25 year's period of time, as a control population for the

1 issues that are coming up.

2 DR. HANAUER: So, a maintenance trial for patients
3 who have responded.

4 DR. RICHTER: Right, yes.

5 DR. WOLFE: I would stress, though, if we are
6 going to use 12 mg as the dose, maintenance studies should
7 be done at lower doses, as well, to see if a lower dose can
8 maintain the patients once --

9 DR. HANAUER: So your concept is a dose ranging
10 maintenance trial.

11 DR. WOLFE: Yes.

12 DR. HANAUER: Loren, any comments?

13 DR. LAINE: I agree with the idea of the long-term
14 maintenance trial for killing two birds with one stone.
15 Personally, if we do approve just 12 mg, would be happy just
16 to have it 12 mg, so I don't think I see any reason to
17 complicate things by going down to 4 mg maintenance.

18 DR. HANAUER: Comments on this end?

19 DR. WISON: The lowest maintenance dose possible
20 would certainly -- since we will be dealing with young
21 women, I would favor looking at the lowest possible doses.

22 DR. HANAUER: Other comments? Dr. Ferry, would
23 like to try it on children?

24 DR. FERRY: I am so glad you brought that up.
25 Thank you very much. As a matter of fact, there are some

1 issues in children that this drug might be very important
2 for. I think there is still some confusion in children
3 whether younger children actually have irritable bowel
4 syndrome, but there are some very close similarities with
5 chronic recurrent abdominal pain, which is often accompanied
6 by mild constipation.

7 I think there are some very clear-cut indications
8 to study this in children, because I think there is going to
9 be a great interest in pediatric GI people finding some
10 solution to a disorder we have absolutely no treatment for
11 at all, that is very chronic and disabling in terms of time
12 lost from school.

13 So, yes, I think pediatric studies, and I am
14 thinking of the age between 5 and 12, not adolescents so
15 much, but the younger children.

16 DR. HANAUER: From the pharmacokinetic and
17 pharmacodynamic data that you have seen, do you think
18 additional dose ranging studies are going to be necessary in
19 kids?

20 DR. FERRY: I think they probably are. For one
21 thing, just looking at the data presented for men, where the
22 drug doesn't work, but the weights are considerably higher,
23 so I think figuring out a weight/kg dose for children is
24 going to be important, so, yes, there are going to have to
25 be some dose ranging studies in children and

1 pharmacokinetics to prove just what really works, and also
2 in a younger age group, the question is going to come up
3 about the type of vehicle to deliver this drug, as well,
4 whether it can be crushed, mixed in syrup, just whatever, so
5 there are other important issues about how to deliver it.

6 DR. HANAUER: Do you think there might be gender
7 differences in children as there are in adults?

8 DR. FERRY: I have no idea, although I will tell
9 you, chronic abdominal pain is more common in girls in our
10 practice than it is in boys.

11 DR. HANAUER: So, you would try to get an adequate
12 sample size of both genders?

13 DR. FERRY: I would, yes.

14 DR. WOLFE: The prepubertal, too? Do you see the
15 same thing?

16 DR. FERRY: With recurrent abdominal pain?

17 DR. WOLFE: Yes.

18 DR. FERRY: Yes, it is prepubertal, and
19 adolescents tend to have a pretty, in my experience, typical
20 adult pattern irritable bowel syndrome. Under age 12, this
21 recurrent chronic abdominal pain has never responded to any
22 of the medications that adults have used traditionally
23 without any proof of efficacy. They don't respond to fiber,
24 they don't respond to anticholinergics.

25 Our postulated mechanism is that there is a

1 heightened sensory reception in the pain fibers from the
2 autonomic nervous system and from the gut to do this, which
3 maybe makes this drug an even better drug for children.

4 DR. WOLFE: Would there be any reason to do some
5 studies again men, using even higher doses, to see if men do
6 require a higher dose?

7 DR. HANAUER: Do you think so?

8 DR. WOLFE: I think it would be worth a try.
9 Again, the problem when we had that low a response rate and
10 took that many that will show it, it is going to take more
11 men to show it, and I think possibly higher doses.

12 DR. HANAUER: Let's ask Dr. Camilleri that, get
13 him back into this. One issue is are we dosing high enough
14 in men, does the peristaltic activity that has been
15 demonstrated in the clinical studies, the nonclinical
16 trials, is that the same in men as it is in women, or is
17 there a gender difference regarding that?

18 DR. CAMILLERI: Regrettably, the sample size in
19 those mechanistic or pharmacodynamic studies is too small to
20 really tell, but I think the point raised by Dr. Wolfe is a
21 very relevant one, as is the point by Dr. Ferry, that dose
22 responsiveness is almost as important as adequate sample
23 size in this case.

24 DR. HANAUER: Other comments? Michael.

25 DR. WOLFE: As long as Dr. Camilleri is up here,

1 is it worthwhile to get more convincing data? It is not
2 going to make a difference in approval, but I would like to
3 see really a cross-over design study to see again, just to
4 add more information, although we may have it with the
5 maintenance study, if we place certain people on drug, put
6 them on placebo, and see what happens to them. That may
7 answer the question and again kill two birds with one stone.

8 DR. HANAUER: That would also be addressed in the
9 maintenance trial where patients are re-randomized, and you
10 would see whether or not there is a "rebound" effect.

11 From additional studies, I would also recommend
12 that the sponsor be a PRN versus a continuous use. My sense
13 is that the majority of the physicians, the consultants are
14 looking to use this for intermittent symptoms and allow
15 patients to use it intermittently and assess the quality of
16 life compared to those who are getting a placebo .

17 I think that would address the questions, many of
18 the questions that we have asked.

19 DR. WOLFE: Is our charge also to make
20 recommendations regarding, not advertising, but how the drug
21 is promoted, because I don't think we should think give the
22 impression to anybody that this is a replacement for fiber,
23 for example. This is adjunctive therapy to people taking
24 fiber.

25 DR. HANAUER: That certainly is an important point

1 since the patients in the clinical trials were treated, were
2 continued on their fiber therapy.

3 Do you want to comment on that Lilia?

4 DR. TALARICO: In a way, yes, it would be an
5 adjunctive therapy to whatever the other treatment for IBS,
6 but I have another question. The modification in the
7 labeling, mention was made for the use of this drug for
8 current symptoms of pain and constipation rather than the
9 pattern.

10 This would change the indication in the sense that
11 it would limit to the time when the patient is actually
12 experiencing the constipation.

13 DR. HANAUER: Right.

14 DR. TALARICO: What is the committee's suggestion?

15 DR. HANAUER: I think we agree with that. Again,
16 one of the issues is we don't want to see patients continued
17 on this necessarily through diarrhea, because that doesn't
18 make sense.

19 DR. TALARICO: The discontinuation when the
20 symptoms subside is one thing, but the initiation of the
21 treatment only when currently, the patient is experiencing
22 pain and constipation rather than the patient having IBS
23 with the pattern or predominantly by pain and constipation.

24 DR. HANAUER: I think the bottom line is -- and I
25 don't want to speak as a whole -- but my interpretation of

1 the data is that part of the reason that we see such a
2 modest benefit is that it is a very heterogeneous group, and
3 a lot of these people who are entered in the trials were
4 what we would consider alternators rather than constipated
5 patients. I see the most important benefit in the patients
6 really who were constipation-predominant, which is not the
7 patients who swing from diarrhea to constipation, who I can
8 envision being one week getting Zelmac, the next week
9 getting another drug.

10 DR. TALARICO: But again, when should the patient
11 start the treatment or limit the treatment if the patient is
12 diagnosed with IBS, predominant, characterized by pain and
13 constipation, can faster treatment just based on the
14 diagnosis and the pattern of the IBS or just because --

15 DR. HANAUER: I think that is an excellent
16 question and let me try and rephrase louder, so the
17 committee can hear this.

18 You are trying to ask can you really treat IBS
19 consistently based upon a historical pattern.

20 DR. TALARICO: Exactly.

21 DR. SURAWICZ: I thought you were asking can you
22 treat acutely or maintenance.

23 DR. TALARICO: Well, either way, when should the
24 patient receive this if we limited the administration of the
25 drug to 12 weeks because the trials were done with 12 weeks,

1 if we allow the patient to stop the medication when the
2 symptoms have subsided, when should the patient start the
3 treatment?

4 DR. SURAWICZ: I would go back to what I learned
5 when I was a student on Surgery from our chief of Surgery,
6 that you can't make an asymptomatic patient feel better, so
7 I would opt for treating when there are symptoms, and not
8 treating when they are asymptomatic.

9 DR. HANAUER: Unless you do demonstrate a
10 maintenance benefit, until you demonstrate a maintenance
11 benefit.

12 Joel.

13 DR. RICHTER: I like the last ramification that
14 the company gave us, where they emphasize IBS patients who
15 currently have a problem with constipation. I think that is
16 the group we are talking about at least initiating this
17 therapy for whatever period of time one wants to use it.

18 DR. TALARICO: That was the point

19 DR. WOLFE: As long as you are talking about other
20 studies and what would help, I think, the company and help
21 all of us are outcomes and cost analyses to show that
22 treatment does not only make the patient feel better, which
23 is very, very important, but also, as was shown in the very
24 beginning, decreases days lost from work, increases
25 productivity, and decreases all the indirect costs

1 associated with this disease.

2 DR. HANAUER: Yes, I was intrigued by the company
3 saying that this was a \$12 billion disease. My sense is
4 that if this is improved, it is not going to be an \$11
5 billion disease.

6 DR. RICHTER: I mean I would emphasize the same
7 thing that Mike did. I really think these maintenance
8 studies are going to be important because it allows you to
9 look at a couple of things, and critical in the maintenance
10 studies is going to be the use of some quality of life
11 indicators to really see how these people are doing, and
12 also attempt to do some type of a cost analysis data based
13 on recurrent visits to physicians and studies being done.

14 DR. HANAUER: I agree.

15 DR. HOUN: Let me just summarize that the original
16 Novartis proposal for it to be approved for IBS in patients
17 who identify abdominal pain/discomfort and constipation as
18 their predominant symptoms, I believe the vote was -- I have
19 7 no and 1 yes, is that correct?

20 However, in discussion of labeling, is it the
21 committee's sense that should the indication change --

22 [Electronic interference.]

23 DR. HOUN: [Continuing] -- for people who
24 currently have these symptoms, that with those kinds of
25 changes, the committee is favorable for that indication?

1 DR. HANAUER: Any dissents to that? Yes.

2 DR. LAINE: I mean we have a dissent about the
3 efficacy, but assuming it's being approved, I would agree
4 with that, but the only thing I would want to make sure in
5 that wording --

6 DR. HANAUER: Wait. You are the dissent. Given
7 those stipulations --

8 DR. LAINE: I think it didn't change on my
9 original vote, but given the fact that it is going ahead --

10 DR. HOUN: No, no, no. I think if you still feel
11 that the benefit-risk ratio is unfavorable, because efficacy
12 wasn't demonstrated, you should state that. I am just
13 saying for those of you who felt the benefit-risk ratio is
14 favorable, those are the kind of changes you folks are
15 interested in.

16 DR. LAINE: Two comments. One, I mean I didn't
17 change my efficacy vote, but the one point I would make, and
18 that is I would just want to make sure that constipation has
19 to go along with abdominal pain/discomfort.

20 I mean just the way you read it, I wouldn't want
21 people to think they could use abdominal pain/discomfort or
22 constipation. I mean it's really people who have abdominal
23 pain/discomfort and also have constipation. So, I would
24 just want that to be very clear in any labeling.

25 DR. HANAUER: Dr. Smith.

1 DR. SMITH: In the studies presented, all three of
2 them, the mean age of the female patients was 43 to 45 years
3 of age, which is really past the child-bearing age, but as
4 you extend the utility of this agent, and it becomes
5 available especially to OB-GYN physicians treating generally
6 a younger age group, you are going to have the issue of
7 pregnancy while taking the medicine become more important.

8 There was only a handful of pregnancies out of
9 2,000 patients, about 20 pregnancies perhaps, but as the age
10 wear, and these ladies all had an average duration of the
11 disease of 13 or 15 years, so you are going to see it being
12 used in women in their late twenties and thirties, who are
13 clearly of child-bearing potential, and that is going to be
14 an issue that everyone is going to have to consider.

15 DR. HOUN: So, are you recommending a pregnancy
16 registry?

17 DR. SMITH: I would think so, just as you have one
18 for Prozac, the initial data showing that it was increasing
19 the risk of miscarriage, and subsequent data showing no real
20 increase.

21 DR. HOUN: Just a final issue was if the drug
22 should be approved and the labeling was revised, there was
23 some discussion and dissent in terms of should it be short
24 term versus no statement of term, and that is how I think
25 the committee --

1 DR. RICHTER: Didn't we vote on that issue,
2 though, wasn't that issue 5 to 2 or 6 to 3?

3 DR. HOUN: Six to 2.

4 DR. HANAUER: Any other questions? I think we
5 have been through your list. Anything else from the Agency
6 that you would like to clarify from the committee, use us?
7 Use us or lose us.

8 DR. FERRY: One other question I had that I don't
9 think we addressed, but I was just wondering if we should
10 consider making a suggestion in the labeling about if
11 diarrhea does occur with this drug, that the drug be
12 temporarily stopped.

13 DR. HANAUER: Makes sense.

14 Other comments? Joel.

15 DR. RICHTER: Are we going to do part (b) of 5?

16 DR. HANAUER: I assume we had done it because we
17 modified the thing, but go ahead.

18 DR. HOUN: I think the people who voted no should
19 suggest studies that would increase their confidence for
20 efficacy.

21 DR. RICHTER: I mean I would like to see a single
22 U.S. study, because this drug, we are the FDA or we are
23 making advice to the FDA for the United States, a single
24 U.S. study which shows efficacy without having to do a post-
25 hoc analysis, and I personally think that should be done

1 with 12 mg, the higher dose, give you the best chance, and
2 also use both a general assessment of pain, as well as a
3 pain-specific score for your two primary efficacy points.

4 I am very bothered that we are talking about -- I
5 am very sympathetic to a group that don't have any drugs
6 available to them -- but when you are talking about an
7 efficacy in the individual patient of only 1 to 8, to 1 to
8 15 women being helped, I would like to at least be able to
9 say that there is a U.S. study done properly that shows
10 this, and that would be combined with the European data to
11 show that there is really true efficacy in the U.S.
12 population.

13 DR. LAINE: I would concur obviously. I also felt
14 that I wasn't convinced by the data as presented, and I
15 would have liked to have seen one pivotal trial in the U.S.
16 that really did document efficacy.

17 As I said, there was really only one trial that
18 documented -- there was only one pivotal trial of 12 mg, and
19 it did document efficacy in Europe, but not here. So, I
20 would concur.

21 DR. HAMMES: Along those lines, I would really
22 like to see a cross-over design, they are their own
23 controls, try to get is placebo effect out of the way.

24 DR. RICHTER: I mean the literature -- and Michael
25 and Arnie can comment about it, too -- the literature in

1 pain has been these cross-over designs never work, because
2 they result in an adjustment of your pain scores. You never
3 know how long of a washout period to have.

4 I think the best way to get at this long-term
5 placebo response really is a maintenance, you know, trial,
6 and then see what happens, but in the pain literature, they
7 really try to stay away from these cross-over studies as
8 much as they possibly can.

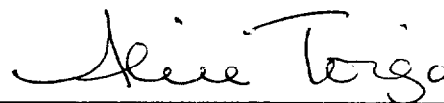
9 DR. HANAUER: With that, I would like to thank
10 Novartis for an outstanding presentation and preparation and
11 being able to address all the committee's questions.

12 We will adjourn until 8:30 tomorrow morning.

13 [Whereupon, at 4:12 p.m., the proceedings were
14 recessed to be resumed at 8:30 a.m., Tuesday, June 27,
15 2000.]

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.

A handwritten signature in cursive script that reads "Alice Toigo". The signature is written in black ink and is positioned above a horizontal line.

ALICE TOIGO

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