

1 effect. However, 10-percent dropout with constipation is a
2 quite dramatic number, too. The only other thing I'd like
3 to bring up that is related to ischemia that I meant to
4 mention is it would be very nice to see flat plates,
5 abdominal x-rays of people; you know, i.e., in a smaller
6 number of people who get constipation, do they actually
7 develop a non-toxic mega colon and have secondary problems.
8 So I think that would be something I'd want to follow up
9 on both related to (a) and (c).

10 DR. WILSON: I basically agree with the prior
11 comments. I don't think the constipation would be a major
12 problem because it was an easy prohibition and it was
13 reversible, it appeared, quite simply.

14 CHAIRMAN HANAUER: I would assume that it's
15 related to the drug.

16 [Laughter.]

17 DR. FERRY: I don't see that as a problem in the
18 approval process.

19 DR. GELLER: I don't either, but I certainly think
20 it has to be mentioned.

21 CHAIRMAN HANAUER: Yes.

22 DR. WILSON: I was going to say that it is, I
23 mean, because they weren't aiming to study that group.

24 CHAIRMAN HANAUER: Okay, nitty-gritty time. In
25 view of the data presented, do the potential benefits of

1 alosetron therapy outweigh its potential risks for the
2 proposed indication; i.e., do you recommend the compound be
3 approved? And then based on that, we have some subsidiary
4 questions.

5 So we'll let Dr. Geller start. Do you think
6 should be--Dr. Geller, do you think it should be approved?

7 DR. GELLER: Yes.

8 DR. FERRY: Yes, I do.

9 CHAIRMAN HANAUER: Yes.

10 DR. WILSON: Yes.

11 DR. LAINE: Okay.

12 DR. BERARDI: Yes.

13 CHAIRMAN HANAUER: You don't get to vote.

14 DR. WALD: Yes.

15 [Laughter.]

16 CHAIRMAN HANAUER: The next component says if not,
17 what additional--we've said yes, but I think we should say
18 do we need additional efficacy or safety data from the
19 sponsor. And I will let Dr. Wald answer that. What
20 additional--even if it's going to be approved, what should
21 we be requesting? Do you want more data on liver toxicity,
22 do you want more data on ischemia, that kind of stuff--
23 pediatric data, old-age people?

24 DR. WALD: Well, I certainly would like to see
25 more pharmacokinetics in women. I think the point was made

1 earlier that the early studies on pharmacokinetics were done
2 in men. I certainly think we need to monitor the drug
3 closely for side effects, particularly the ischemic issue.
4 I'm not so worried about the constipation because it's going
5 to be there, and the liver. I want to see the quality of
6 life data. I think that will be very important. And as
7 just my opinion, in a disorder such as this, I think we
8 should be using that as one standard of looking at a drug
9 like this.

10 DR. HOUN: Could I ask if these additional studies
11 should be performed prior to approval or after approval?

12 DR. WALD: I think based upon what I've seen, I
13 think we could approve the drug with the caveat that we
14 monitor it very carefully and with the expectation that what
15 complications we've seen have not proven too injurious. So
16 I would not hold up the approval pending that data.

17 CHAIRMAN HANAUER: Dr. Berardi, any comments,
18 additional studies that you would like to see?

19 DR. BERARDI: No.

20 DR. LAINE: Besides all the obvious safety stuff,
21 I agree with quality of life very importantly. The one
22 thing again I say, as a clinician I want to know how long
23 I'm going to need to keep this patient on it before I decide
24 it does or doesn't work. That's why I asked that question
25 earlier. You know, do I give it to them for a month and, if

1 it doesn't work, stop? I think that kind of information
2 would be very important to me. This is a long-term--these
3 people are going to be on it a long time, but perhaps there
4 may a subset that do and don't respond and I'd like to know
5 how long I have to wait to determine that.

6 CHAIRMAN HANAUER: I'm not so unclear on that. I
7 interpret the data showing that if they don't respond,
8 they're not going to respond, both by virtue of the three-
9 month total response, all or none, as well as the
10 transitional probabilities that we heard about.

11 DR. LAINE: Well, it looks to me that if they
12 don't respond at a month, they are unlikely to respond
13 beyond a month, is what I'm saying.

14 CHAIRMAN HANAUER: That's my interpretation.

15 DR. LAINE: But I'd just like to have that made
16 clear to me, and I think they have the data and can do that.
17 But that's kind of how I read the data, but I'd really like
18 to know that just to help me manage patients clinically.

19 CHAIRMAN HANAUER: Dr. Wilson?

20 DR. WILSON: I don't think there are any specific
21 additional studies, namely, though, as Dr. Wald said, close
22 monitoring prior to or during the early phases. I don't
23 know how that is regulated, but that would be my
24 recommendation.

25 CHAIRMAN HANAUER: Phase IV studies.

1 I would just add in that because this drug is
2 going to be potentially applied to such a large population,
3 I think that the what appear to be small numbers have a
4 significant chance of being amplified, and particularly the
5 colitic complications and the liver enzymes just need to be
6 watched in the expanded database. And I would certainly
7 want to see as large a database as possible from the
a sponsor.

9 DR. LAINE: So would they.

10 DR. FERRY: I think the only--I mean, the really
11 significant thing I'd like to push would be really careful
12 documentation of any kind of colitis-like picture so we
13 really can clarify what the problem is.

14 DR. GELLER: I'd like to see the results of the
15 year study. I think that that gives much better data on
16 long-term use than we have.

17 CHAIRMAN HANAUER: Before it's approved?

18 DR. GELLER: That's a good question.

19 CHAIRMAN HANAUER: What's your opinion? They want
20 your opinion.

21 DR. GELLER: I'm not sure, I'm not sure. One of
22 the problems is that the only time we have seen that data
23 was today. That's not included in the book, so it would be
24 harder to get a really clear view.

25 CHAIRMAN HANAUER: The obvious question is how

1 close are we to getting that data. If it's next week, it's
2 going to be a different issue. Do we--how long until the
3 one-year data is going to be available? And if I were you,
4 I'd say 12 months.

5 DR. MANGEL: Well, I assume you're referring to
6 the 12-month--

7 CHAIRMAN HANAUER: Long study.

8 DR. MANGEL: --safety data, not efficacy data.

9 DR. LAINE: Right, 12-month safety data.

10 DR. MANGEL: I believe in your briefing document
11 there actually was data included from the 12-month-long
12 safety study--

13 CHAIRMAN HANAUER: Until it's completed?

14 DR. MANGEL: --as to interim analysis. Actually
15 the study is completed now and we do have draft tables. I
16 can't tell you the results of it. We certainly didn't
17 present it because it would have been new information for
18 the FDA that they did not see. The pattern was identical
19 for completion of the study as it was in the second interim
20 analysis, which were the data which you saw and have
21 included. Once again, there were no cases of ischemic
22 colitis reported in the 12-month-long safety study. At the
23 end of the day, that 187 number for completion of 12 months
24 of treatment was now over 300 for 12 months of treatment.

25 CHAIRMAN HANAUER: Yes, Dr. Wald?

1 DR. WALD: I'm just thinking about this. I wonder
2 if there's any data about practical use of this drug.
3 There's nothing to say that these patients should be taking
4 it forever, and since IBS is an intermittent, recurrent
5 problem, I wonder if there's any study going on to give
6 open-label drug to patients with IBS to see how they use it,
7 to give them the option, then, of one, two, or nothing on a
8 given day or a week or something to see what patterns might
9 be established, because patients may well not want to take
10 it everyday even though their symptoms may return. And that
11 might be very important in the post-therapeutic trial to see
12 how we might ourselves begin to use this, let our patients
13 be our guide.

14 DR. MANGEL: You know, we actually do not have an
15 episodic design study underway, Dr. Wald.

16 DR. WALD: You do?

17 DR. MANGEL: No, we do not.

18 DR. WALD: And I'm thinking of another drug in
19 another setting where that is being used, and that might
20 provide very useful data over a year to see how patients
21 would use it and whether that would make a difference.

22 CHAIRMAN HANAUER: Okay. The last question is
23 what labeling recommendations does the Committee have to
24 reduce the potential risks of alosetron, and I'll let Dr.
25 Laine answer that first. He's in the middle.

1 DR. LAINE: To reduce risk, I mean again basically
2 you want to--

3 CHAIRMAN HANAUER: How do you think it should be
4 labeled first?

5 DR. LAINE: Right. I mean, basically it should be
6 labeled for female patients. Obviously, it should be only
7 those who have no hard stool, no constipation or diarrhea,
8 depending on how you want to suggest that. I would probably
9 say no hard stool and no constipation. And I think until we
10 get more information, we have to at least mention especially
11 the colitis issue, say that incidences of colitis were seen.
12 Its association is unclear, but, you know, it requires
13 further study. If something becomes more clear in the next
14 month or two when the information is reviewed by the agency,
15 then that should be incorporated.

16 CHAIRMAN HANAUER: My two cents, and then we're
17 going to zig-zag, is that I think that the labeling should
18 be for treatment for females with irritable bowel whose
19 predominant symptom is diarrhea, period. I don't think that
20 there is sufficient efficacy, nor do I think that the risk
21 has been-- I think the risk is higher in those with
22 alternating, by all that we've discussed, and I would not
23 include alternating stool pattern in the indication.

24 Dr. Wilson, comments?

25 DR. WILSON: Yes. I would agree with those

1 statements, basically, to focus on diarrhea. I'm not sure
2 what language would be most correct, certainly, but to focus
3 on diarrhea.

4 CHAIRMAN HANAUER: Dr. Berardi?

5 DR. BERARDI: I agree with you, Dr. Hanauer.

6 CHAIRMAN HANAUER: Did I give you a chance to
7 answer that, Arnie? Dr. Wald?

8 DR. WALD: No. I think practitioners, at least
9 practitioners who enroll patients here, we think we know
10 what diarrhea is even though we might argue about it. And
11 it would clarify it to say diarrhea, even if you bring in
12 some people who don't quite fulfill that criteria. so I
13 think that's a more specific labeling that would be better
14 for physicians.

15 CHAIRMAN HANAUER: Dr. Ferry?

16 DR. FERRY: Yes, I believe I would include
17 diarrhea. This would be for women with a predominantly
18 diarrhea pattern.

19 DR. GELLER: I agree, but I'm more concerned about
20 what we're going to say about constipation and the other
21 lesser seen side effects.

22 CHAIRMAN HANAUER: So how would you label for
23 contraindications, Dr. Wald?

24 DR. WALD: Constipation, constipation, and perhaps
25 for now evidence of liver disease. You might just say that,

1 if you had someone who had liver disease, we don't know how
2 that is going to play out and they might use that with a
3 little bit of caution. I think that will be very few
4 patients, though.

5 CHAIRMAN HANAUER: Although I presume from the
6 clinical trials that patients with elevated liver enzymes
7 were excluded from entry?

8 DR. MANGEL: Greater--

9 CHAIRMAN HANAUER: Greater than twice normal?

10 DR. MANGEL: Yes, greater than twice normal. If
11 it would help the Committee at all, we do have Dr. Mitch
12 Shiffman here, a hepatologist from MCV who has reviewed the
13 entire LFT database, if that would help with any guidance,
14 if you would have any questions for him.

15 CHAIRMAN HANAUER: I don't think we have any
16 questions for him, frankly.

17 DR. MANGEL: Okay.

18 CHAIRMAN HANAUER: We thank him for being here.
19 Good job.

20 DR. GELLER: I have a question.

21 CHAIRMAN HANAUER: Yes?

22 DR. GELLER: What about patients who have had
23 previous colitis?

24 CHAIRMAN HANAUER: My purview is I'm not opposed
25 to--you know, I don't think that that's a contraindication

1 thus far. I think that there are potential benefits in
2 this, and certainly I think we'll look at it carefully. But
3 I would probably exclude those who have had ischemic
4 colitis, but I don't think it needs to be excluded for
5 patients with inflammatory bowel disease.

6 DR. GELLER: I think we've heard today that
7 ischemic colitis may not be diagnosed.

8 CHAIRMAN HANAUER: I'm not at all concerned that
9 the data is showing chronic inflammatory bowel disease or
10 colitis, and so I don't know that that should be a
11 contraindication to this. For my constituency, who are
12 patients with inflammatory bowel disease, I would not
13 recommend contraindicating it in that population based on
14 the data that we have now. That's my take on it.

15 Anyone else with contraindications besides
16 constipation?

17 [No response.]

18 CHAIRMAN HANAUER: Caveats? Any additional
19 comments on caveats? Dr. Wilson?

20 DR. WILSON: No. I was going to say it was
21 constipation and liver disease. Is that right?

22 CHAIRMAN HANAUER: And liver disease.

23 DR. WILSON: Yes.

24 CHAIRMAN HANAUER: Dr. Senior?

25 DR. SENIOR: Dr. Hanauer and distinguished

1 panelists, there really is no evidence that preexisting
2 liver disease increases the risk of an idiosyncratic drug-
3 induced liver injury, so that if you impose this
4 restriction, you're going to have to do transaminases on
5 everybody before you start the drug.

6 CHAIRMAN HANAUER: But it's very simple because
7 From your standpoint the drug wasn't studying patients with
8 abnormal liver enzymes.

9 DR. SENIOR: I understand.

10 CHAIRMAN HANAUER: So what you see is what you
11 get.

12 DR. SENIOR: Right. I'm not sure that it should
13 be restricted in the way that's being proposed because
14 there's no evidence to support that.

15 CHAIRMAN HANAUER: How about if we say the drug
16 has not been evaluated in patients with abnormal liver
17 enzymes?

18 DR. SENIOR: A precaution should be made, and I
19 hope that if you're going to be watching these patients, you
20 will watch for that as well.

21 CHAIRMAN HANAUER: If we're watching which
22 patients?

23 DR. SENIOR: You said you wanted to monitor the
24 patients for colitis. Well, while you're doing that, you
25 could maybe monitor them also for new elevations of ALT.

1 CHAIRMAN HANAUER: Well, that's a very different--
2 one is a clinical decision, the other is putting a label
3 that will be enforced for physicians to monitor liver
4 enzymes starting this drug.

5 DR. SENIOR: Right, not necessarily in everybody,
6 but perhaps in a cohort.

7 CHAIRMAN HANAUER: I'm personally satisfied--and
8 I'll get the other members--that the drug has not been
9 evaluated in patients with abnormal liver enzymes.

10 Other comments on that?

11 DR. WALD: I'd ask Dr. Shiffman if he would be
12 concerned in someone with preexisting liver disease, not
13 that it increases the risk, but should a complication arise,
14 would they have a more severe reaction?

15 CHAIRMAN HANAUER: See, we got you in under the
16 wire.

17 DR. SHIFFMAN: Yes, I finally made it.

18 CHAIRMAN HANAUER: You've come all this way.

19 DR. SHIFFMAN: I mean, Dr. Senior is exactly
20 right. Patients with chronic liver disease do not have an
21 increased risk for idiosyncratic drug reactions. However,
22 if they have a severe idiosyncratic reaction and they have
23 already established cirrhosis from their chronic liver
24 disease, yes, they theoretically could be at risk for liver
25 failure based upon that.

1 If you look at the data on liver transaminases,
2 there were many patients in this cohort that did have mild
3 elevations in liver transaminases or had elevations in
4 transaminases even up to seven- to nine-fold normal that
5 spontaneously resolved to normal during therapy. And that
6 really speaks to the fact that there's very little inherent
7 hepatotoxicity of this drug, and I think the recommendation
8 proposed by Dr. Senior and the panel is actually reasonable
9 that there's no evidence for--or that the drug has not been
10 studied in patients with chronic liver disease and leave it
11 at that. I don't think it's really necessary to say you
12 need to monitor because there's really no evidence that it's
13 there.

14 CHAIRMAN HANAUER: Okay. Any other caveats or
15 monitoring? Dr. Ferry, anything that has been applied to--
16 it has obviously not been approved yet for use in children,
17 but any caveats you want to invoke?

18 DR. FERRY: No, I don't think so, actually. I
19 mean, I think it needs to be studied in children. I would
20 support it, but I wouldn't add anything. I don't see the
21 liver issue as being any more than what the final comments
22 were just a minute ago. I think that covers it. So, no, I
23 don't see any other limitations related to pediatrics.

24 CHAIRMAN HANAUER: Dr. Geller?

25 DR. GELLER: No.

1 CHAIRMAN HANAUER: Dr. Wilson?

2 DR. WILSON: No.

3 CHAIRMAN HANAUER: It's finally a drug we don't
4 need to study in women.

5 [Laughter.]

6 CHAIRMAN HANAUER: Dr. Berardi?

7 DR. BERARDI: I read this material and I'm pretty
8 comfortable with the lack of potential for drug
9 interactions. But having seen drugs be approved and then
10 months or years later see these incredible drug
11 interactions, I guess that whole issue concerns me when
12 there's one study in healthy volunteers with 15 patients and
13 theophylline.

14 CHAIRMAN HANAUER: Any specific recommendations?

15 DR. BERARDI: Potential interactions with--I have
16 to think about that.

17 CHAIRMAN HANAUER: Okay.

18 Dr. Wald, any caveats?

19 DR. WALD: No.

20 CHAIRMAN HANAUER: Okay, let me ask--yes?

21 DR. GELLER: I have one question. We talked about
22 the drug being given for different durations than tested.
23 We haven't talked about the drug being given to men. Once
24 it's labeled, it can be given to men, true?

25 CHAIRMAN HANAUER: True.

1 DR. GELLER: Should we say here that it hasn't
2 been tested in men?

3 CHAIRMAN HANAUER: Well, I think it has been
4 tested in men to some degree, but there are also planned
5 controlled trials that are in process in men.

6 DR. MANGEL: Yes. In our Phase II program, the
7 efficacy was most clear in females. Considering that there
8 has not been a new drug for IBS for decades, we wanted to
9 focus on where we saw the efficacy. So that's why our
10 initial Phase III program only addressed females. We
11 actually just have recently started a large dose-ranging
12 study in males to make sure that males are not being
13 prematurely dismissed. So I think that answers Dr.
14 Hanauer's question.

15 DR. GELLER: But it doesn't answer the question
16 about labeling for now, does it?

17 CHAIRMAN HANAUER: I think it has. I mean, the
18 labeling is going to be for women.

19 DR. GELLER: Thank you.

20 CHAIRMAN HANAUER: Dr. Senior?

21 DR. SENIOR: Would the learned panel comment on
22 whether the drug should be used continuously, as studied for
23 12 weeks twice a day, or whether the patient should have
24 some opportunity to adjust the regimen? They have proved
25 the dose pretty well, but they haven't proved the regimen

1 what is optimal for management of the patient to avoid
2 constipation.

3 CHAIRMAN HANAUER: Learned Dr. Wald?

4 DR. WALD: Well, I think that was the point I was
5 alluding to before, is that you've established it within a
6 fairly narrow therapeutic range for the purposes of
7 demonstrating efficacy. But it may be that the patients
8 will use it differently, particularly depending on cost and
9 a whole host of things. So I would like to see those
10 studies. I think there probably will be a middle range.
11 I'm sure there will be people who might respond to lesser
12 drugs. I'm sure there will be patients who are willing to
13 take it episodically for episodic symptoms, and I would
14 anticipate seeing it that way, although the initial labeling
15 and indications will be for continuous use.

16 But as I mentioned before, I would like to see the
17 sponsor perform some of those studies as part of an open
18 label process because I think this is a lifelong disease;
19 it's going to recur. To take it daily, weekly, every month
20 or every year after that is imposing a fairly significant
21 burden. It would be nice if we knew that different
22 approaches might be effective. Or perhaps the market will
23 take care of that and physicians themselves will eventually
24 take the lead in doing that. But it's worth considering.

25 CHAIRMAN HANAUER: I would probably leave as the

1 drug is indicated for the treatment of female patients with
2 irritable bowel symptom diarrhea. I would probably add the
3 caveat that in patients who haven't responded over the first
4 month, there's no data that they are going to respond on a
5 long-term basis.

6 And I think that just as Dr. Wald said, the
7 reality is that modifications off of that are going to occur
8 in practice according to individuals. As their diarrhea
9 improves and their constipation comes on, the drug will be
10 discontinued and restarted as they get diarrhea. That's
11 going to be probably how it's used.

12 Dr. Wilson, any comments?

13 DR. WILSON: I guess one thing I was trying to
14 remember from the data of onset of action--if there was
15 efficacy prior to one week, that will probably be some
16 important data because in some of the other drugs we've had
17 people trying to use them episodically but they don't work
18 for 24, 48, one week, or whatever. So it might be helpful
19 for--you know, in the literature that will come about
20 because if anyone ever presumes to think that they are going
21 to tell the patients exactly how they are going to take a
22 medication, they are dreaming.

23 CHAIRMAN HANAUER: Dr. Ferry, Dr. Geller, any
24 other comments?

25 [No response.]

1 CHAIRMAN HANAUER: Can we address any other issues
2 for the agency? We are here at your disposal.

3 DR. RACZKOWSKI: Well, there's still question
4 4(b)(ii), or did the panel already discuss that?

5 CHAIRMAN HANAUER: I thought we had discussed it.
6 Anything else?

7 [No response.]

8 CHAIRMAN HANAUER: Well, with that, first of all I
9 would like to thank the agency for allowing us to be here,
10 the panel for their time and effort in evaluating that, Joan
11 Standaert for her constant supervision of this Committee,
12 and also thank the sponsor for an excellent presentation and
13 an innovative approach to a very difficult problem.

14 We thank you, and we'll close the meeting.

15 [Whereupon, at 3:47 p.m., the meeting of the
16 Advisory Committee was adjourned.]

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C E R T I F I C A T E

I, **VICTORIA RANUCCI**, 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.



VICTORIA RANUCCI

Lawyer's Notes



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