

1 Two of the other cases were very, very complicated
2 -- the lady with multiple adhesions. So, I think we should
3 not be counting all these patients indiscriminately as
4 complications of constipation.

5 DR. HANAUER: Thank you. Yes, Dr. Siegel?

6 DR. SIEGEL: I don't know if I am getting this
7 point correctly, but to me, I don't think it matters too
8 much whether all of those patients were specifically related
9 to the drug in a causal factor. I think that, especially
10 once it becomes a little bit looser in terms of the
11 prescribing, it is important to have some sort of a
12 benchmark so that we can see that when patients who aren't
13 necessarily the perfect patients for these drugs are
14 receiving it, whether we can see, you know, how constipation
15 and those serious complications change when those kind of
16 practice patterns are established.

17 DR. HANAUER: Yes?

18 MR. HAMMES: Obviously, the rate of serious
19 complications that we are seeing enough were enough to set
20 off some flags. I would like to think that the efforts of
21 today are going to decrease that rate. So, I would say
22 let's start where we are and monitor it, and if it goes up
23 from here we have a real problem, and it should go down.

24 DR. HANAUER: Any other goals that the committee
25 would like to address?

1 DR. KENT: I have a question.

2 DR. HANAUER: Yes?

3 DR. KENT: That leads into something you said
4 before that I think is very important. You made the comment
5 before, Dr. Hanauer, that the FDA shouldn't be practicing
6 medicine, and the risk-benefit should be judged in patients
7 for whom the drug is indicated. So, if we are getting
8 complications of constipation because someone with a
9 stricture is put on the drug, what does that mean? What is
10 your view of what that means for the drug?

11 DR. HANAUER: Well, that means that my view of the
12 risk management is that we have to compare the risk to
13 patients in whom it is indicated compared to those who have
14 complications outside of it. That was the point that I
15 personally made to the agency before.

16 DR. KENT: But what is the rate we are trying to
17 decrease?

18 DR. HANAUER: Of complications. Well, we saw some
19 of the complications in clinical trials and we saw some
20 outside of them. So, I think that your question is what we
21 are all grappling with.

22 DR. KENT: Okay. Just one comment, very brief, on
23 ischemic colitis, and that is the whole discussion and the
24 whole aura around ischemic colitis is as if it is an
25 extremely rare event and this is very unusual. But what the

1 data are beginning to show is that ischemic colitis actually
2 occurs relatively frequently. We have a huge program of
3 epidemiologic studies to try and get that rate, and it is
4 not 100 percent sure that Lotronex is actually causing all
5 of these cases, but we do take your comments.

6 DR. HANAUER: We understand that.

7 DR. LAINE: There were zero in the placebo group.

8 So.

9 DR. GURWITZ: I think it is challenging to
10 stipulate benchmarks without knowing the prevalence of the
11 condition in the population and the level of use, and 1/1000
12 may be acceptable under some circumstances but if used among
13 millions of people, then it is potentially unacceptable, and
14 unless we know that, that is an issue.

15 DR. WEISS: I want to take some disagreement with
16 the fact that we should only look at those who are properly
17 prescribed the drug in the risk-benefit equation. I think
18 we have to look at all the people that are prescribed the
19 drug whether or not it is for the indication when we think
20 about the risk-benefits.

21 DR. KRAMER: I want to second that. That, in
22 essence, is a reformation of what I said a little bit
23 earlier. In my opinion, if the overwhelming majority of
24 people who get the drug get it inappropriately because of a
25 misdiagnosis, or whatever, and therefore, the overwhelming

1 majority of consequences is in people who didn't need to be
2 on the drug in the first place, that represents a failure of
3 risk management. I think we ought to take a look at it as
4 risk management, not just what happens in people who have a
5 perfectly accurate diagnosis and have a complication.

6 DR. WELTON: Especially in a disease process that
7 is so hard to really diagnose.

8 DR. HANAUER: Thank you.

9 DR. AVORN: I have another goal of risk
10 management, in response to your question, and that is that I
11 want to come back to the concept of risk in the absence of
12 benefit. I wonder whether there ought to be a way of
13 thinking about the labeling that would encourage doctors to
14 reassess patients after ten weeks of therapy and
15 systematically study whether or not the patient is
16 benefiting, perhaps by a temporary cessation of therapy, and
17 see if the patient continues as well as they were or
18 deteriorates. I think that is a small price to pay for the
19 possibility of getting a lot of patients who may not be
20 benefiting from the drug off the drug. I realize that is
21 not Glaxo's favorite concept, but in terms of not wanting to
22 expose people to any risk if they are not getting a benefit,
23 perhaps there ought to be a protocol that is recommended
24 after twelve weeks, which after all is the main amount of
25 time for which there is data, saying there ought to be a

1 drug holiday and reassess X weeks after that.

2 DR. HANAUER: Along those lines, yesterday we
3 recommended a maintenance trial for another drug. You guys
4 have a maintenance trial going on, a longer than three-month
5 trial?

6 DR. MANGEL: We have a 12-month efficacy study of
7 which we will have the results at the end of July.

8 DR. HANAUER: Thank you. Dr. Welton?

9 DR. WELTON: The problem with the drug holiday --
10 correct me if I am wrong, but I thought your graph showed
11 that the patients all had return of their symptoms with
12 withdrawal of placebo and drug.

13 DR. AVORN: That was average; it wasn't all.

14 DR. WELTON: Average, okay.

15 DR. HANAUER: Any other goals for risk management
16 that we would like to inform the agency of?

17 DR. HOUN: I have a question on death in terms of
18 a goal.

19 DR. HANAUER: Death? That is not a goal.

20 [Laughter]

21 Should we be looking at deaths?

22 DR. LAINE: You should always look at death. It
23 is obviously the most objective outcome. I would obviously
24 look at it, I am not sure that I would include it. The
25 likelihood of showing difference in death, it seems to me,

1 at this time, even in the studies mentioned, is extremely
2 small.

3 DR. HANAUER: We are not worried about dying in a
4 composite.

5 DR. BLUM: Unless it is something to do with bowel
6 disease -- a perforation etc., something of that nature.

7 DR. HOUN: That is what the question was in terms
8 of the complications now show, you know, colectomy, toxic
9 megacolon, perforation. In the future, it is reasonable to
10 assume there will be a death report or more coming in, and I
11 wanted to just make sure that that was discussed here so
12 that when that report does come in the future we have some
13 of your guidance.

14 DR. HANAUER: I think we are going to have to see
15 the deaths within the context. If we see death of a 20-year
16 old with diarrhea predominant irritable bowel from an
17 ischemic event that didn't have any other predisposing
18 factors, versus a 75-year old with diverticulitis who has a
19 diverticular abscess, it is going to impact us differently.

20 DR. WELTON: You are more likely to see it with
21 the constipation patient, not with the ischemic colitis
22 patient.

23 DR. WEISS: But I definitely think you need to
24 monitor the complications and the outcomes of the people
25 that do have those conditions because I think that is going

1 to be very important.

2 DR. HANAUER: That is the next question. The drug
3 was released in February. When is the next time point when
4 the agency should be looking at that? The company tells us
5 that they should have some data by the end of this year
6 regarding some of their trials. Is that satisfactory? Do
7 we need it sooner? Later? We are happy with the end of
8 this year.

9 Anything else, Dr. Houn, on that first category?
10 We can move on? Okay, now we are talking about what
11 interventions in the risk management program should be
12 undertaken regarding Lotronex. Please discuss which risk
13 management tools should be used to reduce the risk and to
14 achieve the desired goals and outcomes. As outlined,
15 various tools -- we have discussed today various potential
16 tools that are not limited to but include changes in the
17 product labeling including boxed warnings, special education
18 programs, the potential of a medication guide, and the
19 epidemiologic studies that have been discussed by the
20 sponsor, and potential studies that could also be done by
21 the agency, and limiting distribution of Lotronex to certain
22 patients or physicians.

23 I think what we will do is take these one at a
24 time for discussion. The first, since it is probably the
25 most important to everybody, is the issue of labeling and

1 whether boxed warnings are necessary at this point. We have
2 heard from the sponsor, for a variety of reasons, that they
3 don't think it is necessary but certainly now it is time for
4 the committee to discuss whether the committee feels a boxed
5 warning is necessary. Let's hear discussions regarding
6 that. Dr. Wolfe, you already preceded this with comments.
7 Do you have anything further to add about a box?

8 DR. WOLFE: I do have one comment. Again, I am
9 not advocating it necessarily, I am just saying it is
10 written down as a consideration. The other aspect that was
11 mentioned I really disagree with is looking at past drugs.
12 Past performance is not necessarily an indication of what we
13 should do in the future. We had a drug recently that didn't
14 have a proper warning and obviously everyone wants to
15 prevent that from occurring again. I don't think anybody
16 disagrees that some kind of warning is necessary to make
17 sure this doesn't actually become a problem.

18 DR. HANAUER: The other options along the labeling
19 that we have heard are increased warnings or highlighting of
20 the warnings, etc. Dr. Kramer, do you have a comment?

21 DR. KRAMER: Well, I will tell you why I lean
22 toward a boxed warning. I learned quite a bit this morning.
23 One of the things I learned from listening to the very
24 poignant stories who suffer with the problem is that there
25 is a sense that even their physicians don't have all the

1 appropriate information to really help them benefit but also
2 prevent their suffering from the treatment itself. So, I am
3 looking for multiple avenues to educate both the sufferer
4 and the physician who is trying to help them, and one of the
5 primary avenues that hasn't been pursued yet is the boxed
6 warning.

7 That is the reason I asked specifically this
8 morning what is the downside, in terms of educating the
9 professional public, to having a boxed warning. Although I
10 recognize it is not an attractive thing to a pharmaceutical
11 company, I didn't hear a specific downside as part of an
12 educational program.

13 DR. HANAUER: I am going to bring the boxed
14 warning to a vote unless there is any other discussion
15 around it. I presume that you guys want an opinion on
16 labeling issues.

17 DR. HOUN: Well, this committee is not really
18 charged with voting because most of the people are guests
19 here. So, what we wanted to have was a brainstorming
20 session, and I suggest that if you did want people to talk
21 about advantages or disadvantages of boxed and you want to
22 bring out people who haven't said things, you can do that.

23 DR. HANAUER: So, we don't have to vote on any of
24 this?

25 DR. HOUN: You don't have to vote.

1 DR. HANAUER: Do you want us to? Do you want a
2 sense of the committee?

3 DR. HOUN: A sense is fine.

4 DR. HAVLIK: I was impressed, actually, that the
5 company had at least gone half the way to a box because, if
6 I interpreted their revision of the labeling, they have it
7 in bold as number one warning that constipation is the thing
8 to worry about. I am not in practice so it is easy for me
9 what I think I would do, but that would certainly get my
10 attention.

11 From the drug company's side, it would seem right
12 now that as much preventive medicine that could be exercised
13 that would not undercut the ability to promote the drug is
14 to the company's advantage. So, I am kind of caught between
15 saying that what I see in the labeling is pretty good versus
16 not really now knowing whether the physicians are going to
17 respond adequately to that. In fact, I had a discussion
18 with a practicing internist who gets bombarded. I won't
19 speak for him but I had the feeling like even a warning
20 might not be enough to get his attention.

21 DR. HANAUER: Well, let's take it right to the
22 proposed labeling and asked for discussions off of that.

23 DR. HOMBOE: I just want to comment briefly. I am
24 the general internist being referred to, but if you look at
25 the data -- and I think we also heard some this morning, the

1 printed materials, whether it be a box or a "dear healthcare
2 provider" letter, don't necessarily work very well. We have
3 seen that in other areas of medicine, including guidelines
4 which are not followed. So, regardless whether you use the
5 black box, I think at a minimum you are going to have to
6 highlight the things you are most concerned about, whether
7 it be a black box, medication guide etc., but you are going
8 to have to take it another step. I honestly don't believe
9 that publishing the stuff and putting it in as inserts is
10 going to be enough. I think it is really going to have to
11 be part of the education program that has been talked about.

12 DR. HANAUER: Well, we agree. We have heard that
13 irritable bowel is a multi-component disease and that risk
14 management is a multi-component attempt at solution, and
15 everything we are going to talk about is assuming other
16 things.

17 DR. WOLFE: One point that was alluded to before
18 was the role of the drug rep. I think you have a program in
19 place, and I think that is very laudable and very important
20 because a lot of physicians get their information from the
21 rep. They have to pass a test to make sure they know --
22 they have to really tell physicians to prescribe this drug
23 appropriately.

24 DR. HANAUER: Let's just go to the label and get
25 some comments on this. Indications and usages -- is this

1 okay, or do you want to modify it or what do you want to do?

2 DR. HOUN: It is fine to get suggestions.

3 DR. HANAUER: You are not thrilled with it.

4 DR. HOUN: The concepts. Don't edit the words,
5 but the concepts.

6 DR. HANAUER: Got that charge? So, the
7 indications -- Lotronex is indicated for the treatment of
8 women --

9 DR. LAINE: Where are we?

10 DR. HANAUER: We are on page five of the draft.
11 Lotronex is indicated for the treatment of women with
12 diarrhea-predominant irritable bowel syndrome. Diarrhea-
13 predominant IBS is characterized by at least three months of
14 recurrent or continuous symptoms of abdominal pain or
15 discomfort and diarrhea with either urgency and/or an
16 increase in frequency. See appendix, and the appendix
17 describes the wrong criteria that support diagnosis of
18 diarrhea-predominant irritable bowel syndrome, abnormal
19 stool frequency, greater than three bowel movements per day;
20 abnormal stool form, loose or watery; and abnormal stool
21 passage, urgency or feeling of incomplete evacuation. So,
22 without talking about the words --

23 DR. LAINE: It is interesting because the
24 indications say three months of basically pain and diarrhea.
25 You know, diagnostic criteria talk about any 12 weeks within

1 the last one year. I am not saying that they are absolutely
2 exclusive but one is stronger, if you will, in terms of
3 talking about diarrhea predominant right in the recent past,
4 while the other one could be read as six months ago, you
5 know, somebody had diarrhea and it is resolved now.

6 DR. KENT: We put it as it is because we felt it
7 was stronger the way it is.

8 DR. LAINE: I like it better in the indications is
9 what I am saying.

10 DR. HANAUER: The next are the contraindications,
11 which are patients with a history of chronic or severe
12 constipation or sequelae from constipation; history of
13 intestinal obstruction and/or stricture, toxic megacolon,
14 perforation or adhesions; a history of ischemic colitis; or
15 known hypersensitivity. In addition, should not be
16 initiated in patients experiencing constipation which they
17 describe as less than three bowel movements per week, and/or
18 hard or lumpy stools and/or straining during a bowel
19 movement.

20 DR. LAINE: Now we are in the recent past, for
21 instance -- in other words, those who had it three weeks
22 ago, I wouldn't include them, as an example, something along
23 those lines.

24 DR. WOLFE: What about alternators, people who
25 have constipation alternating with diarrhea?

1 DR. HANAUER: Is that a contraindication? Is
2 alternating diarrhea and constipation a contraindication?

3 DR. LAINE: What I was trying to say is if they
4 had constipation fairly recently it would be, but if they
5 had it six or eight months ago -- I mean, I am making broad
6 statements, but if they had it a couple of weeks ago, it
7 would be; if they had it months and months ago, it wouldn't
8 be. Again, I am not sure that is based on great evidence
9 but that is what I would maybe suggest to handle that a
10 little.

11 MR. LEVIN: Is there another way to deal with
12 that? Going back to the indications and usage, we said the
13 safety and effective has not been established in men.
14 Should something be said -- the safety and effective has not
15 been established for alternating diarrhea? I don't know why
16 we just pick men. What about all the other conditions?

17 DR. HANAUER: I think that is a very good point.
18 Thank you. Warnings -- gee, I really don't want to read
19 this whole thing. It is on the bottom of page six --

20 DR. SURAWICZ: We have read it; it is good.

21 DR. RACZKOWSKI: Dr. Hanauer, one of the issues
22 that has come up in the contraindications section is the
23 notion of severe constipation as opposed to mild and
24 moderate constipation, and the definition of severe
25 constipation being a subjective one. I wonder if the

1 committee could just give some input about their comfort
2 level with use of that sort of terminology. Is it specific
3 enough or is it satisfactory?

4 DR. HANAUER: Well, my view is that at the top of
5 the contraindications they mentioned a history of chronic or
6 severe constipation. The lower part -- maybe it should be
7 moved up, which is a small point, but it shouldn't be given
8 in anybody with current constipation.

9 DR. SURAWICZ: And you also have the four days.

10 DR. HANAUER: Which is less defined.

11 DR. SURAWICZ: You also have if it doesn't resolve
12 within four days, which is another way that people can
13 measure whether they would fit into the severe constipation
14 group.

15 DR. HANAUER: I mean, the smart way would be to
16 move it closer together because we have heard that we want
17 simplicity for people.

18 DR. LAINE: And, I think that definition is
19 acceptable that they have.

20 DR. RACZKOWSKI: In our discussions with the
21 company, I think one of the main points that has come out is
22 that severe constipation, as intended here and the company
23 can correct me if I am wrong, but it is intended not to be
24 assessed by any objective criteria but by the subjective
25 presentation of the patient saying that he or she -- in this

1 case she has severe constipation, just like if you have a
2 severe migraine or a mild to moderate migraine.

3 DR. LAINE: But, they now define it here. So, as
4 Steve says, if you move this up there is a definition of
5 constipation here.

6 DR. HANAUER: Frankly, we don't know how to define
7 severe constipation. It is a subjective condition unless it
8 has a complication.

9 DR. WELTON: I think that is his point. Then it
10 should be just constipation, not severe constipation.

11 DR. HANAUER: No, we are talking about the
12 contraindications now, with a history of severe constipation
13 or current constipation.

14 DR. WELTON: But what I am saying is that he is
15 suggesting that we should drop the modifier "severe" and
16 just say with a history of constipation.

17 DR. HANAUER: So, anyone who was constipated 20
18 years ago shouldn't be contraindicated.

19 DR. WELTON: That is what his question is, his
20 question is do we know what we are saying, especially in
21 surgery.

22 DR. HANAUER: The next is sort of no-brainer stuff
23 to us. Special education programs -- any comments from the
24 committee? First of all, I will give my personal view that
25 I thought that what I heard from the sponsor was really an

1 outstanding conglomerate of a risk management program from
2 your standpoint. I thought it encompassed a lot of things
3 that we were prompted on coming into the meeting, and
4 incorporated both education to the patients and to the
5 physicians. The key, I guess, that we want to know is that
6 you follow through with that, and that we are being able to
7 monitor that effect along the way. Any other comments
8 regarding the education program that we heard about?
9 Additions?

10 DR. SURAWICZ: Yes, I disagree with you that it is
11 a no-brainer. I think that maybe this is where we could
12 focus a few minutes with brain-storming because, while I
13 like the program that they have, I would like to see them go
14 a step or two beyond and do something that is really new and
15 different, that provides the education to patients directly.
16 They could work with Nancy Norton's foundation. They could
17 work with specialty societies. There are a lot of ways.

18 I think if it is really going to succeed it has to
19 be something different than what we already found worked
20 five percent of the time or didn't work at all. So,
21 educational materials addressed to patients that would be
22 written at a grade five level -- really, really simple; lots
23 of people will understand it; use of visuals, cartoons. Not
24 just translating into languages but really making it as
25 simple and consumer oriented as possible. If you look at

1 not drug advertising but the rest of advertising, it is
2 really, really effective. Maybe building teams with
3 advertising agencies that know how to get to the entire
4 population.

5 In one of these books that I read, and I can't
6 remember which one, there was a list of the specialty
7 societies that are part of a drug complication reporting
8 system. What I noticed in that list of all of the specialty
9 societies was that none of the four GI societies are in that
10 list at all, and that was a real surprise to me, that all
11 these other societies have gotten together to do some sort
12 of reporting of complications. That is not specific to this
13 drug or this company, but something that we might want to
14 look at sometime in the future.

15 So, I would like to see really innovative ways of
16 directing education to physicians, all physicians but
17 especially GI docs, and your primary care docs. Those are
18 your two hugest markets. And, then directly to patients.
19 And, something different. I mean, the examples in the book,
20 to me, of the patient education material -- I think there
21 were five or six examples, and there was one that looked to
22 me, if I were a patient, that I would read. The rest were
23 tiny little types that looked exactly like what I don't read
24 as a doctor and would read even less as a patient.

25 DR. HANAUER: I agree. It is a real brainer.

1 That is why she is going to be the next chairman here.

2 DR. LAINE: And to follow up on a point too, since
3 fortunately or unfortunately a lot of doctors get their
4 information on drugs from representatives, I mean one of the
5 things that the companies do extremely well is monitor drug
6 web visits, to which doctors and what drug they were there
7 for. Although that doesn't tell you how effective it is,
8 one of the quantitative things, I guess, the FDA could get
9 from the company is really having the company commit to X
10 number of visits per physician or per area to discuss this
11 particular drug with these particular educational tools, and
12 just to monitor that and just to make sure that they really
13 are, indeed, following up with educational programs to
14 doctors, or educational material.

15 DR. WOLFE: Regarding educational material, also
16 there are new avenues. You mentioned websites. Websites
17 can be made to have warnings flashing so people can actually
18 see them, consumers and physicians. As far as physician
19 education, I think I can safely assume that all of us here
20 do give lectures that are occasionally sponsored and we are
21 given freedom to say what we want to say. On the other
22 hand, this is something I think should be mandated for
23 physicians who will be speaking on irritable bowel syndrome.
24 If they mention drug therapy, they should mention
25 contraindications during their lectures.

1 The other thing is that there are certain avenues
2 -- Chris mentioned new ways of doing education. One way,
3 for example, is computer programs with different case
4 scenarios for people with certain conditions and how they
5 should treat them, and the kind of patient who would not get
6 that kind of drug. So, there are ways to reenforce the idea
7 of when the drug is appropriately used and when it is not
8 appropriately used.

9 MR. LEVIN: I just want to reemphasize the
10 comments about the Internet because that is really where
11 people are going to get it, and already a tremendous number
12 of people are getting information from the Internet. I know
13 a lot of people don't have access to the Internet yet but if
14 we are looking ten years down the road, that is really where
15 the information is.

16 Imagine my surprise when I dialed up web MD and on
17 their home page, in the left-hand banner is an IBS Glaxo
18 Wellcome connection and you go right to their URL, and it
19 has information but it is also going to tell you about a new
20 product that is available for treating IBS. So, I am
21 concerned that there is a lot of push electronically, and I
22 am not sure that what people can dial up necessarily
23 reflects the discussion we are having today about some of
24 our concerns. For example, if you go on to medscape, which
25 is another of the major websites, and you go to the drug

1 information patient handout for alosetron, it is a very
2 mild-manner statement of the risks. So, I think we have to
3 be aware --

4 DR. HANAUER: Why don't you read it to us, if it
5 is brief?

6 MR. LEVIN: Sure. First of all, it says,
7 important note -- this is intended to supplement, not
8 substitute, for your doctor. It is a one-pager, and under
9 side effects it is constipation, headache, or stomach upset
10 may occur. If these effects persist or worsen, notify your
11 doctor promptly. If constipation occurs, it may only be
12 temporary. If it occurs, your doctor may recommend ... and
13 on, and on. I mean, I think it is a very mild-mannered
14 presentation of the kind of potential severe risks that we
15 are hearing about today.

16 So, how to deal with the information revolution
17 and to make sure that the data that many, many millions of
18 people are dialing up is accurate and presents risk I think
19 is a critical issue.

20 DR. HANAUER: We understand that.

21 DR. KENT: That is based on the original label.

22 [Laughter]

23 DR. HANAUER: We are not holding you to proactive
24 standards yet.

25 MR. HAMMES: I want to reemphasize here the role

1 of the pharmacist in all of this, and to include the
2 pharmacist in this education process. They are the person
3 that is going to see this patient most frequently. They are
4 the professional that is likely to be selling them their
5 laxatives and, if they are any good, they will pick up on a
6 problem -- if they are selling an OTC that is related to
7 this, and it is a good way to get the information into the
8 patient's hands. So, you have to include the education of
9 the pharmacist first off, and I am really intrigued by this
10 medication guide thing. I think you need to force the less
11 than perfect pharmacist to get involved in this. I was very
12 disillusioned with our young lady who told us she didn't get
13 any information because she got mail order. I mean, we need
14 to do something about that.

15 DR. HANAUER: I guess that brings us to medication
16 guides, and we are not taking a vote but are there opinions
17 from the committee members?

18 DR. BLUM: I would like to say one thing about the
19 pharmacists also. The pharmacists are usually in the
20 community, and if you mention language barriers and being
21 able to educate, the pharmacist in a foreign-speaking
22 community usually speaks the language of that community to
23 communicate with the individual. So, they would be the best
24 -- better than any type of print media -- to get the
25 information across. But the pharmacist also has access not

1 only to the OTCs but the herbals that they may be taking,
2 which could interact with all of this.

3 MR. LEVIN: As a veteran of the med guide wars
4 over the this last decade, I would like to strongly urge
5 that the FDA think very seriously about requiring a
6 medication guide for this product. I think medication
7 guides, which establish standards for presentation and
8 content, and format and the graphics are really important,
9 and I think the most important facet is that it requires
10 that risk information be up front rather than buried
11 somewhere down the line. Even though we have this limited
12 approach to medication guides, I think this is a wonderful
13 opportunity to use the medication guide regulation as a
14 public health protection measure.

15 DR. HANAUER: How would you assess that then? How
16 would you suggest that they assess the benefit if they
17 imposed a medication guide?

18 MR. LEVIN: I mean, you would have to have some
19 control to compare it --

20 DR. HANAUER: So, would you suggest a study of a
21 medication guide in one population versus another to test it
22 in one managed care group or another?

23 MR. LEVIN: I am not sure that is how the
24 regulation authorizes medication guides to be used. The
25 regulation that is currently there, from '98, I think says

1 that you can select up to five to ten drugs and then require
2 that a medication guide be provided by the manufacturer and
3 must be dispensed with that drug. So, I don't know if you
4 can parse that into specific populations. I don't think I
5 would suggest we need to study medication guides yet again.
6 We have been there; done that. After all these years of
7 comments and actions by Congress and the agency, comments by
8 everybody, the decision was that where drugs present a
9 certain level of risk it is appropriate to have a medication
10 guide.

11 DR. HOUN: What would be useful in a medication
12 guide intervention evaluation would be to do an audit of
13 pharmacies to see if that is actually happening. Even
14 though regulation means that there is force of law to
15 require this, there is force of law to require you to drive
16 55 miles an hour or less and, you know, whether people do it
17 or not or whether pharmacists do it or not, that could be
18 checked on.

19 DR. HANAUER: Do we have data that these guides
20 make an impact?

21 DR. MORRIS: My name is Louis Morris. I am a
22 consultant for Glaxo, but I am also one of the veterans of
23 the medication guide wars. I worked at FDA and was
24 responsible for heading up that project. Just in terms of
25 some of these questions, just a couple of comments.

1 The first is, as you might guess, there is no
2 guarantee that requiring it by FDA regulation actually
3 results in the distribution of information. As Dr. Ostrove
4 mentioned, there have been studies done, pharmacy shopping
5 studies, where people went in, filled prescriptions for the
6 estrogen patient package insert, which is required by a
7 specific regulation, and somewhere between 20-40 percent of
8 people received that document.

9 On the other hand, there is some evidence that
10 changing the packaging is a more effective solution, and one
11 of the things that Glaxo did not go into detail over that is
12 significant to this discussion is that in the proposed new
13 patient package insert there has been a significant change
14 in how that would be packaged. The current insert is
15 attached in a perforated sheet with the physician insert.
16 The pharmacist has to pull out the physician insert, tear
17 off the patient package insert and hand it to the patient.
18 In the current plan, the patient package insert will be a
19 separate document. It will be attached to the bottle
20 itself.

21 One of the things that we know from the new work
22 that is being done on systems and systems approach to
23 preventing medication errors is that the best solution is
24 the one that fits most easily into the routine practice of
25 whoever is distributing it. In this case, what we have is a

1 pharmacist who simply has to pull the bottle down off a
2 shelf. The bottle for Lotronex, the average size is 60,
3 which is a month's supply, and the majority of prescriptions
4 are at that rate. So, all the pharmacist has to do is take
5 the bottle off and put it in the bag. The pharmacist
6 doesn't have to do anything special to distribute the
7 medication guide. It is actually attached to the bottle.
8 So, I think that packaging solution goes a long way in terms
9 of concerns about getting it distributed, and I think
10 historically packaging solutions have been more effective
11 than regulatory solutions that simply require it.

12 The second point I wanted to make about medication
13 guides is that one of the downsides of a medication guide is
14 that there is a standard format, and that if a medication
15 guide is required, then the company would be required to
16 follow the standardized format. Currently, the company has
17 plans to thoroughly test the information to make sure the
18 message is getting across, and having the flexibility to
19 actually get the message right is one of the concerns that I
20 would have where, if it is a medication guide, it has to be
21 in the standardized format.

22 MR. LEVIN: Lou, I think that is the argument that
23 is always used with any standard or guideline. When
24 guidelines are issued, people say, well, medicine is an art;
25 it is not a science, and you can't stifle innovation. So,

1 there is always a tension between those two sides, and I
2 think we have to recognize that but one doesn't preclude the
3 other.

4 I think the standardization is important because
5 when people go in an survey, even today, the accuracy and
6 completeness of the voluntary medication guides that are
7 available in pharmacies there is a lot of important stuff
8 that is left out. So, at some point in time you have to
9 develop a standard for what is to be included in a
10 medication guide and how it is to be evaluated. I think we
11 have done that ad nauseam since 1995 with medication guides
12 with all the permutations, with all the parties -- two years
13 of the Keystone process which I was part of with all the
14 players at the table, and I don't think we should continue
15 to debate whether there is a reason to try to have a
16 standard medication guide. Whether it is appropriate or not
17 for this particular drug I think is the issue that we are
18 concerned with today.

19 DR. HANAUER: Go ahead.

20 DR. OSTROVE: Can I just had one additional point
21 concerning the standardization issue? Dr. Levin is right,
22 there has been a large history with this. But, I think it
23 is important to recognize that the regulation permits
24 exemptions and deferrals and that if, in fact, the
25 manufacturer has data and is doing research on what best

1 communicates to a particular patient population that shows
2 that a slightly different format would work better for that
3 population, that certainly is something that we would take
4 into account in looking at it. The standardized format is
5 one that we feel is good because that way people can look in
6 particular sections to find out where the particular
7 information is that they are looking for. However, if there
8 is data, then that is something that we will always take
9 into account, and we will not be overly restrictive in
10 determining what is absolutely necessary under those
11 circumstances.

12 DR. AVORN: There are well established approaches,
13 very well known to industry when one wants to sell a product
14 about how do you get information out, how do you make sure
15 the message got through, is it working and if it isn't
16 working how do we change it to make sure that it works.
17 That is fine. I think it is just time to put those well-
18 established approaches also at the service of getting
19 information to doctors and patients about problems with the
20 drug, and that is completely within the purview of what
21 companies know how to do and I think we should expect that
22 they will do it. When we have a drug that is on the market
23 we don't say it makes as a drug, let's just give it to
24 people and not see if it works. We demand that we know
25 whether the intervention is working and I think we need to

1 do the same thing with informational interventions.

2 DR. FISHER: Hi. I am Rosemary Fisher. I am
3 actually here as a consultant for Glaxo. I have a concern,
4 as Dr. Blum did, about the mail order prescriptions and
5 things getting across. I actually wonder whether the
6 attached tear-off on the bottle, 60-pill medication
7 instruction sheet as opposed to a medication guide would be
8 a more guaranteed was of known that in the mail order
9 prescription that would be getting to the patient because it
10 was attached to the bottle, and not having to have somebody
11 who is just throwing things in a box, making sure that a
12 medication guide got in there.

13 DR. WEISS: I am definitely leaning toward the
14 medication guide, and it is something that the company reps.
15 had mentioned, that this condition is really something that
16 the patient goes to the doctor for, and it is the patient
17 that has to recognize whether or not they have constipation
18 and seek treatment for it. And, I think that is the kind of
19 thing that we really need to have in a medication guide,
20 educating the patients, more than the doctors, to seek
21 treatment. So, I can see that that is another way to do
22 that.

23 DR. HOUN: The med. guide could be attached to the
24 bottle, just as the PPI.

25 MR. HAMMES: And why can't we do both?

1 DR. HANAUER: It sounds like we are doing
2 everything -- to them.

3 DR. HOUN: So, I guess the consensus is that
4 people are recommending a medication guide.

5 DR. HANAUER: Not necessarily. I think that we
6 are hearing a composite effect that Glaxo Wellcome has told
7 us that they are doing, and I am not certain that adding
8 everything that you can do up front now is going to be
9 better, worse or -- my recommendation is to look at a
10 variety of different means to assess this. You are asking
11 for risk management which means studying it and imposing all
12 these things at once, you are not going to know which is the
13 best way of making an impact right now.

14 I certainly agree also with Dr. Surawicz that the
15 organization would like to take part -- the American
16 Gastroenterologic Association, the ACG, and the functional
17 research group should also get involved with assessments and
18 education as well.

19 DR. SURAWICZ: I would give the company the
20 freedom to come up with something better than a med. guide.
21 If we don't mandate what they do, maybe they will come up
22 with something really creative and better that will set a
23 standard for the other companies when this comes up next
24 time.

25 DR. HANAUER: I would like to see some studies out

1 of it, which is what you are proposing. You can't assess it
2 unless you are evaluating it in some controlled manner --
3 different modalities.

4 DR. KRAMER: I do have a little bit of a concern
5 about a strategy in risk management which would test one by
6 one by one single interventions, and this where it may come
7 in handy to talk to a communications researcher or a
8 psychosocial researcher. My understanding of the field is
9 that, much like where often one drug at a time isn't the way
10 to treat the whole disease, you need multiple approaches,
11 multiple avenues. So, that issue may already have been
12 sufficiently studied in communications research so that we
13 know that we should expect poor increments with a single
14 intervention, one at a time.

15 DR. BLUM: Just one question on the med.
16 guidelines, does that include the Med Watch number, the
17 telephone number for patients to report or anyone else to
18 report in the med. guide, and should that even be considered
19 as a way of gathering data?

20 DR. OSTROVE: The regulation doesn't include that.
21 It certainly could be included. That is something that we
22 are looking at for other regulations having to do with
23 professional labeling at this point.

24 DR. HANAUER: Besides what we have discussed, does
25 anyone around the table have ideas or opinions as to how

1 they could improve the benefit side of the drug? We have
2 talked a lot today about the risk.

3 DR. WOLFE: Just one last idea, there is a
4 consumer magazine in which patients could actually write
5 their own stories. I think that is one way of approaching
6 it. They can actually state what the disease is and what
7 benefit they have from it, from the different treatments.

8 DR. HANAUER: Anything on the up-side? How can we
9 improve the efficacy? Any specific opinions? I think you
10 have heard that the education is to try and limit the use to
11 the indicated population where we have seen benefit.

12 DR. BLUM: That is the best way because if you
13 don't give it to the right population you are only going to
14 get the downside and it is going to give it a bad rep.

15 DR. HANAUER: Any guidance from the committee on
16 what is the best way to evaluate these interventions? I
17 think, again, we have heard a number of proposed studies
18 from the company. There is a whole variety of different
19 controlled and uncontrolled studies. Anything in addition
20 or preference from the committee members or our consultants?
21 Yes, Dr. Welton?

22 DR. WELTON: When you asked me earlier whether I
23 had any suggestions about what else to look at, it occurs to
24 me, and I don't know how to do this because I have my own
25 area of expertise which is very limited, but it occurs to me

1 that although you may not see vasospasm in some of these
2 studies, you may have a relative ischemia of the mucosa
3 because the studies that were presented back in November
4 suggested that increased uptake of water and increased
5 cellular activity you could have a fixed inflow with a
6 hypermetabolic state, leading to relative ischemia of the
7 mucosa. I can't tell you how to study that particularly in
8 a mouse or a rat model. I have a concern about the PET
9 scans. As far as I know, that doesn't work because there is
10 too much background information, but there may be a way to
11 look at mucosal ischemia and relative hypoperfusion from
12 metabolic activity.

13 DR. HANAUER: Dr. Houn, any other aspects
14 regarding evaluation? It is a very open, broad-based
15 question for us.

16 DR. HOUN: I think one is to reaffirm that
17 interventions that we do institute, you are looking to have
18 us and the company evaluate that effect. That is a new step
19 for FDA because we don't traditionally evaluate a labeling
20 change or an intervention. So, I think the fact that you
21 are expecting to happen is something that I want to
22 reaffirm.

23 DR. HANAUER: Speaking for myself as a member of
24 the committee, I think that that would be one of the better
25 ways, and it certainly would be useful to have an

1 independent demonstration of an effect. You are going to
2 hear about a series of interventions and studies from the
3 company but I think that as long as you are using this as a
4 model, and no drug wants to be a model, I am sure, it would
5 be useful if you developed your own tools to assess and
6 validate what you are hearing from the other side.

7 DR. HOUN: So, one thing I would like to know is
8 if we do undertake an independent evaluation of some of the
9 risk management interventions, I am assuming our labeling
10 will change to outline some of your recommendations for
11 contraindications and for indications, and we could
12 evaluate, either by a chart audit or the automated
13 databases, in fact, is there, like, ten percent or less of
14 patients who are receiving Lotronex having
15 contraindications, conditions, or other medications. We
16 could do that kind of a study, and is that something you
17 would be recommending in terms of appropriate and safe use,
18 that type of an evaluation of practice?

19 DR. HANAUER: Yes, but I would also urge you to do
20 it by physician specialty because, like in anything else,
21 the specialists are going to try and push the bubble more,
22 probably with more experience in doing that than the primary
23 care physicians. Other comments?

24 DR. WEISS: I would like to see, if you do a
25 medication guide or package insert, that the patient

1 actually gets it and that they actually understand it. I
2 think, from what Dr. Rodriguez showed us, that that is
3 probably an important step to take.

4 DR. AVORN: I think also some survey methodology
5 of both patients and doctors to understand not just what are
6 their behaviors but what they know because you want to know
7 what the doctor is telling the patient in the office about
8 the side effects. Again, I would just turn to the industry
9 and ask how they evaluate how well a direct to consumer
10 advertising campaign is working and use that exact same
11 methodology.

12 DR. HANAUER: The last point we need to go over is
13 if you don't do what they say, what next. What do you want
14 to know, Dr. Houn?

15 DR. HOUN: Let's say we do make contraindications
16 for people who have had severe constipation or constipation
17 in the last three weeks -- I mean, those are very defined
18 terms, and we find that, gee, when we do our evaluation 50
19 percent of patients in this study who had, in fact,
20 contraindications were getting the drug, or we look at
21 adverse event reporting -- right now we have six cases, of
22 which three had constipation, and if we look at the numbers
23 of contraindications on adverse events, are they decreasing?
24 If that doesn't happen and if you could set up some
25 acceptable levels to achieve, and if those levels are not

1 achieved, what would you recommend? Would you recommend at
2 that time going back for another year doing education? Do
3 you recommend -- shall we reconvene the committee next year
4 to reassess the programs? If we are finding that GI people
5 have less rates of contraindications, should they be the
6 ones that prescribe this drug? So, that is what we want --
7 we want to push you further. You said all these lofty goals
8 about education, do right, no more, you are going to be
9 better -- how about if it doesn't happen? What should we do
10 next?

11 DR. HANAUER: Well, my answer is going to be
12 simple. It is just what we are asking of the sponsors.
13 When they come to us with studies and we learn from each
14 study, and we learn what is good and what is bad and then we
15 redesign based on that. I think it is going to be difficult
16 to do that without the specific information that we get out
17 of these maneuvers. Dr. Ferry?

18 DR. FERRY: Yes, I would like to second that. I
19 mean, this has been difficult enough today --

20 [Laughter]

21 -- it may not be that clear-cut, you know, a year
22 down the road either. I think we are going to have to
23 reassess it at the time. I would have a terrible time
24 coming up with some pre-plan that if this doesn't work you
25 have to take some other major step.

1 DR. SIEGEL: One point on that, I am hearing a lot
2 of tension between, you know, hearing the importance of
3 really being sure that the drug is prescribed correctly to
4 the people for whom it is really indicated and, yet, there
5 may be some groups of physicians who want to push the bubble
6 a little bit and they really know enough to be prescribing
7 it in different ways. I think we have to be very clear up
8 front, if you are looking at that kind of an evaluation down
9 the line, of whether you really did want to hold the line or
10 whether it really was okay to push some of this prescribing
11 a little bit by certain subgroups of physicians or by any
12 physician. I think that the real issue there comes down to
13 tying it to the rates of problems that you are seeing at
14 that point, but it seems to me that if we sit here and say,
15 well, if we find a problem later on, but we haven't actually
16 defined up front whether that is a rigid goal that we have,
17 you are not going to be in a position to say anything
18 different in a year from now.

19 DR. HANAUER: I don't understand that.

20 DR. SIEGEL: Let me see if I can clarify it. We
21 have made some points here on how important it is for this
22 drug to be prescribed precisely for those patients for whom
23 it is indicated, that is to say, in terms of, you know, not
24 having a history of constipation and other predisposing risk
25 factors that would potentially give them problems. Yet, if

1 it is being prescribed -- and the point you made, unless I
2 misunderstood it was that some specialty practices may have
3 a patient who does have a history as an alternator, or
4 something like that, but for whom there is really nothing
5 else, and they are suffering and they are in terrible shape,
6 and they really do want to give this patient a trial on the
7 drug, and then they have a problem. I think that we have a
8 tension there. I mean, we have said that a critical goal
9 for this drug is that it be restricted and prescribed
10 according to --

11 DR. HANAUER: I think you misunderstood what I was
12 saying, which was that since you are studying it one of the
13 ways to assess is by physician group and within and without
14 the indications. So, we are saying very much the same
15 thing, that we need to evaluate where the complications are
16 coming and where the benefits are coming.

17 DR. SIEGEL: It may be that we are saying the same
18 thing --

19 DR. HANAUER: I don't feel tense about it.

20 DR. SIEGEL: That is good. No, my concern is if
21 you are thinking about what is the next step, it is going to
22 be confusing data a year from now if we haven't reached some
23 of the benchmarks that we were aiming towards, but part of
24 the reason for that is because certain people have really,
25 with great consideration, decided to use the drug in

1 different ways, and there is no barrier to that happening at
2 this point.

3 DR. WOLFE: Are you saying that now, for example,
4 50 percent of the cases were due to people using the drug
5 incorrectly and next year you want it to be 25 percent only?
6 So, that shows an improvement and that the program is
7 working.

8 DR. HOUN: I can't say that I have thought through
9 exactly what those guidelines will be. I think that we did
10 talk about having a benchmark and looking towards
11 improvement toward that benchmark but, at the same time, I
12 think that there has been no statement here that it should
13 be in any way restricted so that people won't be using it
14 for some patients for whom they think it is particularly
15 indicated, and with an illness like this where people don't
16 have a lot of choices, I think it is very likely that people
17 will push those boundaries.

18 DR. HANAUER: How else can we advise you?

19 DR. HOUN: Dr. Wolfe, did you have a question?

20 DR. WOLFE: Are you looking for guidelines from
21 us?

22 DR. HOUN: That would be great, if people have
23 some suggestions.

24 DR. WOLFE: The only way to assess this is
25 looking, I guess, at prescribing practices to see who is

1 getting the drug but also the complications. I think that
2 is what we are going to be looking at to see if people who
3 had complications were, indeed, inappropriately prescribed
4 the drug. Again, the confounding factor, as has been
5 brought up, is that some people may just want to try
6 anything they possibly could. Maybe in that case a consent
7 form would be necessary.

8 DR. BLUM: There is one other thing, trying to get
9 physicians in the office but most of these complications are
10 going to occur, especially the constipation -- getting them
11 to report, say, to Med Watch or someone else because that is
12 really your population of under-reporting. It will occur in
13 that population.

14 DR. AVORN: The web MD interface that Mr. Levin
15 told us about is something which, clearly, the company is
16 eager to take advantage of, and maybe the agency may want to
17 talk with the company about other ways in which that
18 collection of names and addresses, phone numbers and e-mail
19 address which are being assembled can be used for collecting
20 data proactively, as well as for marketing, and I think that
21 could be a very nice tool that could be used for a number of
22 different purposes.

23 DR. WELTON: Is there a minimum of workup that we
24 are going to say needs to be done when a diagnosis is made -
25 - again, ischemic colitis?

1 DR. HANAUER: By the physician?

2 DR. WELTON: If a patient calls in and says they
3 are having some bleeding, does the prescribing physician
4 have to work that up?

5 DR. HANAUER: That can't be regulated. Do you
6 have a comment?

7 DR. GURWITZ: Yes, the only thing I just want to
8 reiterate as far as next steps is how important it will be
9 to find out what the patients and providers understand about
10 the educational program. If you see a reduction in
11 complications, then you can say the program is working and
12 that would be okay, without understanding potentially what
13 it was about it that worked but just know that is worked.
14 So, it would be particularly important if you get back here
15 in a year and you find out things aren't better, and if you
16 don't know what the providers and patients understand
17 despite all your databases and stuff you are going to have a
18 hard time deciding what your next steps are going to be
19 because you are not going to know what part of the message
20 they did or did not get.

21 DR. HANAUER: Okay. I want to thank again the
22 company, Glaxo Wellcome, for their presentations and their
23 willingness to work with us and the committee to try and
24 compact the discussions. I hope we have not influenced in a
25 negative way. I think we squeezed this lemon as much as you

1 can get out of it today.

2 I want to thank personally Dr. Talarico for
3 supporting me during my chairmanship here, and Dr. Gallo-
4 Torres, and we look forward to the reign of Dr. Surawicz for
5 the next meetings. Thank you, all. Have a good night.

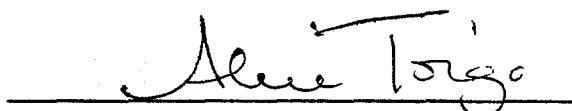
6 DR. HOUN: Thank you so much.

7 [Whereupon, at 3:30 p.m., the proceedings were
8 adjourned.]

9 - - -

C E R T I F I C A T E

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



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