agree that a consumer, and even I have a problem looking at that table and understanding the rates in the comparator columns that he had pointed out earlier, so.

DR. CANTILENA: Yes, Dr. Blewitt?

DR. BLEWITT: Yes, I, I agree with Dr. Johnson though, and I agree with the point that's being made, but if the data are quote flawed, which is a term that I've actually used myself, if there are better data that exist, or if there are better ways to find out what, what the real data are, then, you know, that would be the ideal situation, but I think to take data that, or, I ask that the sponsor speak to this, too. If these are not hard data, then you're taking soft data or inferential data it sounded like to me and now you're making it more consumer friendly. So I don't think that that accomplishes what you want to accomplish either.

I, I agree that in a situation like this, you know, where pregnancy is the risk, if you will, that the women should understand what the comparative benefits are, of products are. The question is how good are the data, the comparative data that they're trying to interpret.

DR. CANTILENA: Yes, you know, actually,

I have a, a question if I can ask the, the folks on the committee who actually practice in this area just to get sort of your read. Are the numbers that are in that table, Drs. Greene and Lerner, are they within, you know, the ballpark, or --

DR. LERNER: No.

DR. CANTILENA: Okay. Could you, could you comment a little more on exactly what you mean by, you know, they're not in the ballpark and especially if there's a way in which you can present, you know, relative information.

DR. LERNER: In, in our out-patient clinic which is just a very typical, you know, low socio-economic Medicaid type patient population, we have a beautiful poster -- I don't know the source of the poster; I'm sure I can find out -- that actually has all the benefits and, you know, sort of the advantages, the disadvantages, a little, pretty graphic on all the different methods. And the, you know, estimates on efficacy rates. And you know, that's sort of what we, you know, use in all our, you know, OBGYN techs.

I'm sure the American College of OBGYN or the, you know, family planning organizations must have reasonable data. I'm sure there's data out there,

other than Contraceptive Technology, not that I'm belittling that, but I kind of am. That I think that as a much more global scope, that we might, or you might sort of do an, a detailed in-depth review of some of the references and just try and find out with some, you know, find out some reasonable numbers and then just, you know, put them in all of the, all of the inserts as needed because I, I don't think they are.

You know, we quote, you know, roughly what we've seen which is barrier methods, roughly in the ten percent range, so to think that the Today Sponge has 40 percent, which was listed on that, just is really way out of, of the realm of what we, we sort of quote to patients and our estimates.

DR. GANLEY: I think in the one column that was pointed out were typical use rates, and you know, I would agree with the comments earlier. But I think something like the lowest expected rate of pregnancy, is that way out of the ballpark? Where it actually lists the vaginal sponge as nine percent?

DR. LERNER: No, that's reasonable.

DR. GANLEY: Yes, that's what I'm, so there is some information there that shows you in terms of order magnitude compared to other methods.

DR. LERNER: But then the table needs to be modified.

DR. GANLEY: Right, I'm --

DR. LERNER: No, then the table needs to be modified.

DR. GANLEY: Right, I --

DR. LERNER: And just, you know, we usually quote, you know, abstinence, a hundred percent, you know, tubal ligation, you know, 99.5 percent, OCPs 98 to 99 percent, you know, condoms, diaphragm, you know, everything, withdrawal, you know.

DR. CANTILENA: Okay. Further comments, Dr. Greene? Would you like to add to that?

DR. GREENE: Yes, I'd, I'd like to address that. I certainly agree. I think that the numbers quoted here are way out of line and much higher than we would normally quote our patients. And most reference material that we would use, certainly, the American College of OBGYN does have a, a patient information literature that has numbers that don't resemble this even closely.

I would like to revisit, since we're at this point, the issue that was brought up a little earlier, which is your denominator. And I would certainly favor or recommend that the, sort of the

industry standard is how many pregnancies occur among a hundred women using the method for one year, a hundred women years.

Now, that can be made, that can be made readily understandable for patients. And the problem of having less than one woman per hundred women years is understandable. Patients understand that. And whether it's one in a thousand or one in two thousand, most women don't worry about those differences too much. If you just say less than one woman in a hundred using the method for a year, people understand that.

And with that as the standardization, I think you could get numbers here that are very easy for lay people to understand, and much more in line with what we generally quote our patients.

DR. CANTILENA: Okay, thank you very much.

DR. LERNER: And just one further thing. I, I do assume that we use all the American College of OBGYN. They have tons of patient and physician information stuff, so I, I do encourage you all to sort of look into that.

DR. CANTILENA: Okay.

DR. GANLEY: Yes, I just want to point out one thing that, you know, Dr. Greenslade hadn't really

touched on. And one of the reasons, I think, in our proposed labeling where it said one out of ten is we really didn't know where that rate came from and what it was pertaining to, because if you actually look at the current labeling, it's written as in clinical trials of today, vaginal contraceptive sponge since 1979, over 18,000 women worldwide have completed over 12,000 cycles of use. The results of these clinical trials are as follows, pregnancy rates per 100 women. And they just list them.

And I think it goes back to what Dr. Chin had reported, that when this was initially approved, if you remember, the, the pregnancy rates, it was 12 month pregnancy rates. And then a year later, we're just talking about pregnancy rates without any time frame. And that's why, you know, we went through the regulatory history, because we're a little confused as to what rate we're talking about there, too. But I think we understand your point.

DR. CANTILENA: Okay, Dr. Uden?

DR. UDEN: If I can -- are we done with that? Because I wanted to ask a question about the allergy alert, so if we're not --

DR. CANTILENA: Is this a question that's you know, specifically to FDA?

the toilet inappropriately or into a garbage can or wrapped up or whatever. But children see those as attractive nuisances, as disgusting as that might seem.

I guess my question is in your passive surveillance system review, did you find -- I'm not worried about the toxicity of, of at least, the parent product. But did you find any instances of, of choking among small children at all, who might have gotten these, chewed them, swallowed them and had a problem?

DR. KARWOSKI: We didn't go and look at those specifically, but the lowest age that we found for an adverse event report was 12 years old, so I would assume that no, we haven't had any reports.

DR. KRENZELOK: Okay. Thank you.

DR. CANTILENA: Okay, what I think I'd like to do now is move actually to the charge to the committee by Dr. Ganley and then we'll still have ample time for discussion prior to going into the questions.

DR. GANLEY: Yes, I'm just going to keep my remarks brief since I had made some earlier remarks to try to focus the discussion. I think the one thing I, I just want to emphasize again that, you know, one

of our purposes for reviewing the entire data base is as a division, we weren't familiar with this product. And so we weren't familiar with the safety of the product. And we thought it warranted a safety review to see if the other information needed to be included in there.

In doing that, I think we developed a comfort level that there was still a benefit, the risk benefit still favored this product to be marketed. That's number one.

And I think the other thing that I want to make a point of that in the years since the sponge discontinued the marketing, the, the agency has gone to great lengths to try to improve the OTC labels. And we've developed standards now that are actually in the codified regulations.

And so, I think our position is that we should try to improve this label before it goes back on to the market, once they get their chemistry issues resolved. And we can just go to the questions now.

And these are just the questions that we had brought up. And one was given the material provided in your briefing packages and presented today, does the revised labeling adequately convey the risk associated with the use of the product? The

current carton label does not contain information on the efficacy of the product.

Should the carton label include efficacy information so that the consumer will have this information available at the point of purchase? And I think in writing this question, we were focusing more on the information that had come from the clinical trials, rather than the comparative. But if you want to comment on the comparative part -- and we were looking at more in the vein, I think, of what is currently on the topical minoxidil for hair growth as providing that type of information.

And if, yes, it's this type of information, should it be on other OTC products? That's the important thing there.

Are there other aspects to the labeling that we, that should be revised? We're interested in any comments. And the other thing is to please provide comments on the type of post-marketing surveillance for adverse events the sponsor should conduct. And I think the reason for that is, as Claudia had pointed out, as years progress, the reports that have come in have been lesser quality. It's very hard to look at these things as a safety reviewer and make some determination of causality.

And we, we think it's very important that these reports, if they're, if they're given to a sponsor, be well written, someone follows up on them, collects information and then provides them to us.

I think the other issue is the type of information we should ask in terms of the company getting calls from consumers about difficulty removing the sponge. And how should that be cataloged? What kind of follow-up should be provided? Should the company contact the consumer a day or two later just to see that everything's okay? And those are the types of things that I think we're interested in. Thank you.

DR. CANTILENA: Okay. Thank you, Dr. Ganley.

I think, actually, just before we go to the, to the specific questions, what I'd like to do is invite the committee, actually, individually. We'll sort of go around the table, just to offer sort of general comments regarding some of the issues in terms of what they've seen. Some of, you know, the conflicts that, you know, they've identified, and then after we go around and everyone's had a chance to sort of air their concerns or express their opinions regarding sort of the global issues, then we'll come

back and go through the questions, one by one. So we'll, actually, if you don't mind, perhaps we can start over on this side. Dr. Krenzelok, if you'd like to share with us your thoughts at this point without actually specifically answering questions.

DR. KRENZELOK: All right. Thank you very much.

Just a couple of things that have, have sort of dawned on me as we've discussed this. From the standpoint of, of this as a, a package that might contain three or six or nine or twelve sponges, as I stated earlier, it seems to me like there needs to be information on each and every sponge that talks about how to use the product properly and so on, rather than there being a single package insert for the container. Again, given the portability of them and the ease of taking them and throwing them into a purse or a briefcase or something of that nature.

Another thing that, that I'm sensitive to, again, working in a, in a 24-7 type of situation is the fact that I think here's an opportunity to be very proactive with surveillance. So that in sort of a passive way, to have 24-7 availability, not just through pagers, but have a real live body there, a competent person. And one of my thoughts on that is

perhaps that it might be wise to out-source something like this to a nursing triage service, like Ask-A-Nurse, who's there's 24 hours a day, seven days a week as a, as a possibility.

And then the other thing along those lines, and, and it's been addressed before is the importance of some of those people having bilingual capabilities, at least Spanish and English for this country. So those are just the thoughts that I had.

DR. CANTILENA: Great. Thank you for those comments.

I guess, you know, one possibility would be to out-source through a poison control center.

(Laughter)

DR. KRENZELOK: That would be a conflict of interest.

DR. CANTILENA: Dr. Blewitt, would you like to share with us some comments?

DR. BLEWITT: I guess my, my own observation at this point is that the issues are very, very narrowly focused now. I don't see a great deal of difference between the sponsor and, and the agency on, on, on the principles involved in the labeling. It's just a matter of how those things are worked out.

The only thing that we haven't discussed,

and I don't know whether it's up for discussion. But in the review package, there's a consumer information leaflet. And there's, there are about three pages of --

DR. CANTILENA: Can you help find us that --

DR. BLEWITT: Well, two, two pages. This is in the section on 2000 label submission, and it comes after the drug facts labeling. And, again, I don't know if this is up for discussion. But it seems to me that as I read through this, I had a few concerns, that it's been significantly edited. It's been, as far as I can see, substantially expanded in size. And I'm, without getting down to the details of it, a question again arises as to whether the consumer's receiving too much information here.

So I, for instance, on -- well, I will give you a for instance. There's a comment in here you can avoid the risk of getting sponge-associated TSS by not using the sponge. Well, that seems to be a rather reasonable and unnecessary statement. I mean, you won't get it if you don't use it, for sure.

But the, the major point is that there are a lot of red additions. There are black, there are deletions, but it's a much larger consumer information

leaflet than it was originally. And without being judgmental about it, I would just ask people to consider whether that's just overloading the consumer with information to the point where they won't read it.

DR. CANTILENA: All right. If you use, if you use headers in the format, though, isn't, you know, isn't it sort of easier to, to help sort of the scanner to be able to?

DR. BLEWITT: I have no question about the, the format. It's, it's only in terms of the amount of content, the volume of content.

DR. CANTILENA: Great. Thank you very much, Dr. Blewitt. Dr. Johnson, would you like to share some comments?

DR. JOHNSON: Most of my comments probably relate specifically to the questions. I mean, I think that it's pretty clear that this is a safe product, and that there's not much question that another contraceptive method for women is a good thing. And so, I think that it, it really does seem to be just a matter of working out the, the little details in the labeling.

DR. CANTILENA: Okay. Dr. Uden?

DR. UDEN: The only thing I'll add is, is

I'm concerned about the consumer comprehension of the present label. The old one, the new one that's been submitted, suggested by the FDA and that, that maybe a consumer comprehension study needs to be done to determine whether they can, somebody can understand it. And, you know, maybe it needs to have cartoons on, cartoons in the, in the package insert so that people can really understand how to use it.

DR. CANTILENA: How do, how do you feel the 2000, you know, proposed label compares, you know, to the '91?

DR. UDEN: Much better.

DR. CANTILENA: Dr. Williams?

DR. WILLIAMS: I agree with what has been said previously. I have no new, I guess, information, more than I've used in the past. I've used this product when I was in my practice and it was available. So we were very conscious of the pitfalls about the use of it as well as the literacy of the patients that we had to deal with who had to come in contact with it. And so we had to use more counsel in our private office to, to ensure that they knew well about this product. So I think the cautions have been expressed are ones that I, I concur with.

DR. CANTILENA: All right. Thank you very

much.

Dr. Davidson?

DR. DAVIDSON: Well, I'm pleased to hear everybody actually making some redundant conclusions. You know, I'm going back to, to the clarity of the message, you know. I don't mind if we have more material. It's up to the patient to read what we give them, you know. But there are some messages that need to be clear, and I think we clearly stated what are the messages that, that need to be out there.

I want to remind that the translation to Spanish needs to be friendly, you know. It needs to be basic and to the point. And, you know, not to forget that we really want to have an 800 number that covers minorities as well.

DR. CANTILENA: Okay. Thank you very much. Dr. Lerner?

DR. LERNER: I made plenty of comments so far. You know, again, I think it's great. I think one of the most important aspects will be that 800 number. And I don't mean to sort of trivialize your intention or purpose, but I think that that's going to be, I think our main concerns are the toxic, toxic shock and the questions of removal. And that clearly is going to be where the patients head first.

So I think they're going to, the training of people is going to be very important. Additionally, I think just, I can't overestimate where the placement on the label or on the carton needs to be. There's a, a section that just sort of said questions and comments, but that sort of didn't give it enough impact. I know within the, you know, narrative it said, you know, if you have trouble removing it, call the, the talk line. But I think maybe if the phone number is written in, you know, larger font or bolder numbers or something. Just sort of if the patients are ill or having problems, they can just key right into it.

DR. CANTILENA: Dr. Gilliam?

DR. GILLIAM: A couple comments. The first goes back to one of the earlier speakers today, talking about incidents of vaginal irritation if it's used for several days in a row. And, on a quick glance, I don't see that that's really mentioned in the package insert, and possibly that should be added.

I do think that a efficacy statement should be added. And I like the one that Dr. Greenslade had used earlier.

I think there should possibly be stronger warnings not to use it while a woman in menstruating,

and possibly move that statement up to underneath the toxic shock. Or, in addition, as a lot of the women that do, did get toxic shock, it happened, they were menstruating and using the sponge. And they were not, they were, shouldn't have been doing so.

And then lastly, I, I think that there really needs to be a package insert in the carton in both Spanish and English, since you can't really control the distribution of the product in, because of our growing Hispanic population in this country. That's all.

DR. CANTILENA: Thank you. Dr Greene?

DR. GREENE: I'll reserve my specific comments for the answers to the questions. I just generally feel strongly that this should be made available, and I don't think there's a big difference between the sponsor and the agencies, just a matter of getting the details of the wording of the insert and the carton.

DR. CANTILENA: Thank you. Dr. Neill?

DR. NEILL: A couple of questions that will help me in later answering charge three about specific items of the label to be revised, and I'll direct these to Dr. Krenzelok. I'm less worried about children eating these than sex partners, and I'm

wondering -- I have no idea about the toxicity of nonoxynol-9 or the sponge itself, which I presume would simply be passed right out the other end when it ends up in the mouth and alimentary tract of a sex partner. Do I need to be worried about nonoxynol-9 when it's ingested?

DR. KRENZELOK: No, it's, it's very innocuous, from my experience. As a toxicologist, that is.

(Laughter)

DR. CANTILENA: Thank you for adding that clarification.

(Laughter)

DR. CANTILENA: We were starting, starting to worry about Pittsburgh.

(Laughter)

DR. NEILL: Well, since you brought it up, Ed, you know, the other question that came to mind aside from this, you know, oral ingestion that I had was in occupying my mind with all of the different permutations that might occur in the course of sex as it happens, I was -- and this does not pertain to any of our charge. It was just I thought interesting and maybe a little entertaining. I was wondering what happened to the efficacy of this product with food,

alcohol, any or all of the above in many different kinds of combinations. Please, don't anybody feel compelled to answer that. And then, I've got a couple other specific questions that we'll get to when we get to the charge.

DR. CANTILENA: Okay. Thank you very much. I think in the, in the interest of time, I'll, I'll just reserve my comments to, as, as they sort of pertain to the questions. So if there are no other issues that people want to discuss, why don't we proceed with the questions then?

First question, given the material provided in your briefing packages and presented today, does the revised labeling -- and here, we're specifically talking about the 2000 proposed labeling that's in your document -- adequately convey the risks associated with the use of the product?

And what I'd like to do is, this is a yes, no answer. And as opposed to going around the table, why don't we just ask for a show of hands. So all those who feel that the answer is yes, that is, the revised labeling does adequately convey the risks, please raise your hand.

(Hand vote taken)

DR. CANTILENA: It looks like nine. Okay.

All those who feel it does not adequately convey the risks.

(Hand vote taken)

DR. CANTILENA: One, and can I ask you to actually comment in terms of what is, you know, missing?

DR. KRENZELOK: I think that, that the information about toxic shock should be emphasized in bold so it really stands out. That's the only reserve I have.

DR. CANTILENA: Okay. Thank you very much.

Second question is the current carton label does not include information on the efficacy of this product. Should the carton label include efficacy information so that the consumer will have this information available at the point of purpose? So, specifically, we're talking about including efficacy on the outside, on the carton, as opposed to on the inside, in the package insert.

And here, again, I'd like to ask for all those who answer in the affirmative that the label, the carton label should include efficacy on the outside, please indicate by raising your hand now.

(Hand vote taken)

DR. CANTILENA: Okay. Nine in the affirmative, and can I ask Dr. Neill, I assume you're voting no and not abstaining. Could you tell us, you know, what your concern was?

DR. NEILL: If we include only efficacy on this product, and we say this is effective -- in 100 women years of use, there will be X many pregnancies and do not include information about other products, I don't know that I or consumers would naturally come by the information to make that isolated nugget useful.

If we include the other comparative information, that's something, given what I understand now about how Rogaine and some other medicines have been marketed, that I don't feel comfortable getting into.

I mean, that gets to the second part of this, which we'll get to in a minute, which is, if yeah, should it be required of all OTC contraceptive products. If the answer to the first part is yes, there's an implied question in my mind which is okay, what kind of efficacy. And that's going to require a whole another day of hearings.

And I think we also need to take into consideration the comments that were made very early

today about the extent to which our discussion of inclusion of that information on all OTC contraceptive products would require that kind of process. I think that it's probably that important.

DR. CANTILENA: So, so you're saying then if, if the information on the outside was comparative in nature and valid, I assume, then, you would favor that. And, you know, as it is, in isolation with, you know, one and ten, it's not adequate, or it's not advisable.

DR. NEILL: Well, I, I would not oppose -- well, it's nine to one, so it doesn't matter what I think, but --

DR. CANTILENA: It always matters.

DR. NEILL: Oh, of course. All right. I think that if it's just in isolation, that might be preferable. As somebody who has to counsel patients all the time, I actually find it less useful for me to say, or incompletely useful for me to say this is, you know, will result in X numbers of pregnancies per 100 women years. But rather, I find it more useful for me to put my patients' risks in the context of the risks that they face daily in their life.

I, for -- I don't like telling my patients and having them think this is a very risky thing, if

they don't understand that walking across Market Street outside my office is even riskier. Do you understand what I'm saying? And that --

DR. LERNER: Just, just as a comment with that, I think that the decisions here are made at the corner drug store at 3:30 in the morning. And so I think that as much information as we can provide, comparative or otherwise, is going to be much more than they're going to get, you know, beeping any of us at that time of the morning.

DR. NEILL: I guess, then, my plea would be to include meaningful, comprehendible efficacy data. For something where the outcome is as measurable as a pregnancy, that's useful. The difficulty for the agency, I think, is going to be for OTC products for which this may become an issue, for which there's an outcome which is much more subjective, like Rogaine.

DR. CANTILENA: Okay, I guess, can we ask another question then, Dr. Ganley, of, of the committee and, you know, regarding the format of the information, whether it's now comparative or just, you know, isolated for the product? If, if you're not opposed, then I would like to propose a question to the committee then. If efficacy label, if, if the

efficacy information on the outside of the carton contained, you know, comparative information to other methods of information, would you favor it included on the outside of the carton with this product?

DR. GANLEY: Can, can I just make a comment for anyone?

DR. CANTILENA: Okay.

DR. GANLEY: I'm, I think the one thing that we have to be sensitive to is that the size of these boxes are a certain size. And there's so much information you can get on it. And I think you have to take into account that if you're going to put comparator information, it is going to take up a lot of room. And so, I think you need to keep that in mind when, you know, if, if -- and that's, that's become a problem for us in, and certainly, I think that Allendale would agree with that. And if there's another way to show or to direct a consumer to the package insert, I think that, you know, that we, we cannot forget those things, that there's a limited size on these boxes.

DR. CANTILENA: I guess the --

DR. GANLEY: Unless we just sell 12 packs, or 18 packs or something.

DR. CANTILENA: Yeah, I guess, I guess,

you know, the reason I was suggesting, you know, this question is really at, at the time the consumer is making the choice about, you know, purchase, should they know how this compares to other methods, which are over the counter or, or otherwise? And that, but, I guess it's sort of a, a hypothetical because, all right, you know, obviously if, if the box has to be, you know, five by six feet in order to get all the information that, it would not be a practical thing. So I guess that's where that where was coming from. Any other, any other comments? Dr. Johnson?

DR. JOHNSON: Well, I think, already in the package insert, there's a statement this is much less effective than the pill and IUD. So it might be possible to put on there in 100 women over one year, you would, there would be approximately ten pregnancies. This is much less effective than hormonal methods such as the pill or Norplant and the IUD. And I think, you know, that doesn't go into a lot of real specific comparator data, but does give, give them a point of reference. Because I think most women understand that the pill was a very effective birth control method and can sort of use that as a comparison.

DR. CANTILENA: Yes. Dr. Lerner?

DR. LERNER: But sort of to answer the second part, the part A, and then sort of reflect it back, I think that if we say then that we do agree that this kind of information should be required of all over the counter contraceptive products, then we can sort of, or you guys can sort of make some sort of standardized mechanism so that you can put it in a certain sort of well-circumscribed way that's consistent so that when the consumer is going down the aisle, you know, there's sort of a particular place that they can look and see, you know, the comparative efficacies, and therefore, sort of save room, sort of in the same way that you'd go down and look at the saturated fat in your Snackwell cookies or something, you know. Just sort of the number of grams or whatever per any given serving.

DR. CANTILENA: Okay. Well, then, how about if we -- I'm sorry. Dr. Neill?

DR. NEILL: I, I similarly would favor a condensation into a single sentence which made sure to include the other OTC. If the point is to allow people to make a decision about condom, semicid, foam, jelly or sponge versus, you know, pill, et cetera. While pill's important, if they're there at three in the morning, they ain't going to get it.

The, the other issue related to this second part of the question -- I'm trying to imagine how, in the bathrooms of all of the gas stations that I stopped at on my way to Tennessee, the condom dispensing machine is going to include that comparative information for shelfkeeping units are like, that are a single condom. And I don't know, does, you know, this doesn't need to be addressed right now, but I could imagine that for some of the other forms that aren't as bulky and don't have the advantage of having a six-pack box that it might raise some more practical issues for them, more so than the sponge. And it's just something to sort of keep in the back of the mind.

DR. CANTILENA: Okay. Well, how about if we actually call that question that I posed, which is basically to have the comparative efficacy available on the outside of the carton with all the caveats in terms of how it should be simplified, et cetera, et cetera, which I think is an excellent comment. All, all in favor of having the comparator information on the outside of the carton, please raise your hand.

(Hand vote taken)

DR. CANTILENA: Dr. Davidson, did you vote? Yes?

DR. DAVIDSON: No.

DR. CANTILENA: Okay. So we have nine in favor, and perhaps I can just ask you to comment why you did not.

DR. DAVIDSON: You know, I, I think it's important but I think that, you know, we can have that information inside. If you give the information of that product on the outside, because if you look at the package, you know, there's other more important information that should be outside, including you're going to state that this is not a 100 percent effective, you know. For, for the information, see the package insert. You know, I think we need to make it a little simpler for the people, you know, that buy these products. Otherwise, if you put a lot of information outside the package, you know, people are going just to read a couple of things and then no more. That's my recommendation.

DR. CANTILENA: Okay. Thank you. I believe we haven't formally answered 2A although we started to a couple of times. 2A, if yes -- yes, meaning it should be on the carton, should this kind of information be required of all OTC contraceptive products? And again, we'll first ask all those in favor of having it available on all OTC contraceptive

products, please raise your hand?

(Hand vote taken)

DR. CANTILENA: I think this time we are unanimous. Okay, the next question, question three, are there other aspects of the labeling that should be revised? And here, I guess, we'll just open it up to comments, perhaps going around the room, starting around this side with Dr. Neill. Any other aspects of labeling that should be revised when we're now, our frame of reference is the 2000 label?

DR. NEILL: Yeah, I have I think three questions that I would propose be considered for inclusion in the section, other questions you may have. The first is what if it comes out? I realize that difficulty with removal is, you know, the single biggest complaint or reason for phone calls, but if it comes out, can you put the same one back in? Do you have to use a different one? If it comes out and you don't have another one, is that the end of sex?

The other question would be, there's just two, not three. It's related to one that Dr. Gilliam asked a few minutes ago. Can this be used several days in a row? And I think that would also allow an appropriately prioritized discussion of the extent to which increased sensitivity may occur if it's used

several days in a row. My perception being, yeah, certainly, it can be. However, you may experience more irritation with this. And I think that's a valid concern that needs to be in there somewhere.

DR. CANTILENA: And here, you're talking about in the package insert and not the label? I mean the front part?

DR. NEILL: In the package insert, right.

DR. CANTILENA: Right. Thank you. Dr. Greene, any, any comments about other issues of labeling?

DR. GREENE: Not really; just minor. I was glad to see under six, there are other questions you may have, that the first thing it addresses is the use of a latex condom. And I do think that's important. And the only minor sort of editorial suggestion is that in that section where it says will help reduce the risk of transmission of human immunodeficiency virus, HIV, and acquired immune deficiency syndrome. I, I would just suggest that that just be changed to read the virus that causes acquired immune deficiency syndrome. That's just technically a little more correct, but I don't have any major problems.

DR. CANTILENA: Thank you very much.

Dr. Gilliam?

DR. GILLIAM: Just the comments I, I made earlier, especially regarding the irritation and stronger warnings not to use during menses.

DR. CANTILENA: Dr. Lerner? No further comments. Dr. Davidson? Dr. Williams? Dr. Uden?

DR. UDEN: Only that I think it could be written in a lot less technical terms than what it is, so.

DR. CANTILENA: The insert, the?

DR. UDEN: Yes, the package insert, yes.

DR. CANTILENA: Thank you. Dr. Johnson?

DR. JOHNSON: My comment is primarily a practical one regarding what goes on the outside of the box. And it has to do with the directions. I mean it's not very clear to my, me, why we need to tell them on the outside of the box that they need to wash their hands, wet the sponge, put the, the dimple side facing up.

I mean, it seems to me if you're trying to save space, those are things that someone will look for once they buy the package, once they open it and they're ready to use it. So it seems like you could get rid of a lot of the things in that direction section. And then you would have more room for things

like how effective is this product, which I think is much more important.

DR. CANTILENA: Yes, follow up to that, Dr. Neill?

DR. NEILL: Yeah, I -- while there's probably room for some editing there, I think at least part of the purpose is to allow people to make a decision about whether they want to use it. And if there's an advantage to having that kind of explicit direction, it's that some consumers may see that and decide as a result yes, they really want to use this, as opposed to another method or they really don't want to use that. And simply directing somebody to the package insert inside removes that portion of the information that helped them use it.

And, you know, it's just, who knows whether that would be the major contributor about a decision to purchase? Personally, I think for information on the outside of the package, if the FDA or somebody doesn't say something about where the price sticker goes, everything we're talking about means nothing. And I'm not suggesting that we talk about where the price sticker goes.

DR. CANTILENA: Further comments, Dr. Johnson? Thank you. Dr. Blewitt? Dr. Krenzelok?

Yeah, I guess, really, I would concur with a lot that has been said. I, I would also just, under number seven, points to remember, it's not, it doesn't jump right out at you that the product needs to be left in place for six hours after the last act of intercourse. And I, I would understand, or I understand that if you remove it shortly after, it's high likelihood to, you know, not be effective.

So if there's some way to emphasize that clearly on the insert. It, you know, doesn't have to be on the outside, but just to make sure that people don't use it like some other methods where, you know, you remove it right away after you -- yeah, it's, right. But it's sort of, you know buried down there. And that's sort of the final point, so if there's some way to emphasize that, that I think would be helpful.

DR. UDEN: Can I make a comment on that? Because what that does is effectively you cannot have sexual intercourse from 24 hours to 30 hours. So if somebody has it from 24 to 30 hours, they can't leave it in for six more hours. So this is only good for sexual intercourse for 24 hours, and then it has to be left in. And then there's that window there where they're not supposed to have sexual intercourse if they're going to follow the directions explicitly.

DR. CANTILENA: Yes, Dr. Johnson?

DR. JOHNSON: I, I did find one other thing I wanted to comment on. And that was the pregnancy rate tables. I mean, I think I sort of made it clear I really dislike that table, one because I think they can't understand it. And secondly, because it sounds like the data has at least some problems.

And I think certainly we need some comparator data, but I think written in the form that Dr. Greenslade suggested is, is much more useful for the patient.

DR. CANTILENA: Okay. Thank you. What I'd like to now do is just turn to the final question. And I know the hour is late, but I would really ask your, you know, patience to, to really give this some thought because I think it's possibly a very important issue.

Question four, please provide comments on the type of post-marketing surveillance for adverse events the sponsor should contact, excuse me, should conduct. And here, we have issues of active collection, follow-up reporting analysis of cases of difficult sponge removal, provisions in place and, to facilitate adequate adverse event reporting.

So again, we started here last time.

DR. UDEN: Yeah, I don't think we should hold them to a higher standard. I mean, unless this question, I mean if, if we did, then we would be setting a precedent for every, every product that would come in front of this advisory committee or in front of the FDA from here until the end, I would, I would assume. I mean, what would be special about this product that we would ask this versus other products that might, that might become OTC? Other than that comment, I just hope that the sponsors would have complete and consistent information in, in their system, so that it's as complete as possible.

DR. CANTILENA: Thank you. Dr. Williams?

DR. WILLIAMS: The only concern I have is to look at the CDC data as that comes available regarding the reintroduction of the product. We have a reportable disease and that could be easily monitored.

DR. CANTILENA: Thank you.

Dr. Davidson?

DR. DAVIDSON: I agree with everybody but, you know, one thing I forgot maybe for the low literacy people, you know, a video on how to use the, you know, the device will help us. And I don't know if the sponsor is willing to, you know, make a video

for those very low literacy people.

DR. CANTILENA: Thank you. Dr. Lerner?

DR. LERNER: Well, we've discussed a lot about the consumer hotline. But I think also a physician hotline or some way to get the practicing clinicians, you know, sort of plugged into the system so that when they do encounter any adverse outcome, there's a, either a phone number or something accessible -- medical letter or in the journals or however you do that with other stuff.

DR. CANTILENA: Thank you. Dr. Gilliam? No further comments.

Dr. Neill?

DR. NEILL: I would never make it on Jeopardy pushing this button. The, it's a generic comment that has to do with the repetitive nature of this question which I think goes to the question of the MedWatch system. If I were to ask my residents, okay, what's MedWatch, you know, I'd get a 1 out of 36 response rate. And, so generically, I guess I would put in a plea to the agency or some higher up muckety-mucks that have, you know, budget dollars to do whatever might be done to help improve that system as a monitoring system given that it's, you know, relying on lazy physicians like me to both understand that I'm

seeing an adverse event and pick it up and report it.

And I realize that there have been a lot of things done to make that easier. I used to literally go and photocopy the little form out of the back of the PDR. But I threw all the PDRs out of my office because I hate them as a drug reference and have taught my residents not to use them. And so now, we've got to go to the web and do all this other stuff, and then the network's down so, again, just a long plea, you know. Whatever you can do to improve that, make it easier, market it.

Here's a, here's an idea. We can take these FDA NDA fees and take a portion of those or, you know, we can always hit the sponsors up for something, right? Rather than making them pay for an adverse, an active adverse event reporting system, we, we take some portion of the money that we, I mean ask from them for their NDA and put that specifically towards some of this MedWatch -- I don't know, a MedWatch czar or something, however that works.

DR. CANTILENA: Okay. Thank you very much. I, I guess I would only add just a couple of small comments on this issue. One, one is, you know when I hear a couple things about being a small start-up company and all the employees being here at the

meeting, I get concerned that the follow-up and, you know, safety is not going to be adequate. I'm sure that the plans would be, and I would hope that, you know, you would have agreement on this with, with the FDA that as it goes on the market or hopefully just before the cash flow starts that you would clearly invest in having adequate, you know, facilities, adequate, you know, personnel. And just make sure there's a very tight, you know, linkage between the 800 number and follow-up and the adverse events.

And, and I would say that even because this has not been on the market for basically five or six years, it's an opportunity to see how well the system actually works. So even if you could agree on perhaps, you know, quarterly reports instead of annual reports to see sort of the linkage between the 800 number and the adverse events and, and the follow-up on the adverse events.

And I would just, as some free advice to the sponsors, invest in quality individuals who have experience in this area because it'll, you know, make, you know, your job a lot easier, and all the people who are watching a lot easier as well if there's good, you know, documentation and follow-up. So that's my two cents. Now, I guess, I'll, I just have to ask the

FDA if there are any other issues that we have not addressed, any questions that were not adequately answered that you'd like us to address at this time?

DR. GANLEY: No, I think we got an idea of what your position is, and we appreciate all the comments. I, I think Dr. Neill made a interesting point there, you know, about the reporting to FDA. And, and one of the things that was not included in the, the labeling rule was a requirement to include a MedWatch number on there. And I get a sense that you would actually, or to have some information that you could, if people could complain to FDA, if not to the sponsor.

I'll just point out that the questions and comment portion of the labeling is not required unless the sponsor decides to do it. In the NDA route, we can more or less encourage them to do it but in the monograph system it's not a requirement for a company to do that.

DR. NEILL: I wouldn't suggest putting the MedWatch number anywhere, I mean, if it were going to be any place, it ought to be on the actual product itself that gets pulled out in the emergency room at three in the morning. So, you can say, oh, I'm suppose to call so and so. With the other obvious

places for that to be -- would be, you know, in more generic education programs and that would require, I think in about, you know, how do we get physicians to change behavior and good luck.

DR. CANTILENA: Well, on that pleasant note, why don't we adjourn for today and thank you very much for your attention and all of your comments.

DR. TITUS: And would the Committee please take their information off the table because it's going to be reset before tomorrow morning. So, take -- you can leave your name tags and your name plates but take any of your paper with you, please.

(Whereupon, the meeting of the Nonprescription Drugs Advisory Committee regarding Labeling Issues on the Today Sponge, was concluded.)

CERTIFICATE

This is to certify that the foregoing transcript in the matter of: NONPRESCRIPTION DRUGS ADVISORY COMMITTEE MEETING ON LABELING AND REMARKETING ISSUES - THE TODAY SPONGE

Before: FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

Date: WEDNESDAY, JULY 12, 2000

Place: BETHESDA, MARYLAND

represents the full and complete proceedings of the aforementioned matter, as reported and reduced to typewriting.

Rebecca Davis

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