DR. DAVIDSON: Okay. Do you understand that? In regard to labeling the concern is that the conditions and cautions in the clinical trial protocols should be provided as information in the patient information leaflet, such as chronic conditions and over 35 and smoking -- those have not been tested.

DR. HENDERSON: I think adolescents also have not been tested.

DR. O'SULLIVAN: There are a couple of other things that I would like to bring up. Some of them are wording issues and labeling that I had some difficulty with or the way it should perhaps -- may own peculiarities.

DR. DAVIDSON: This is the time to bring them up.

DR. O'SULLIVAN: Yes, well, there are quite a few. I do not know if you want to go through all of them.

DR. RARICK: Are you suggesting specific wording?

DR. O'SULLIVAN: Yes.

DR. RARICK: If you have a general concept that you would like us to work on or if you could give us a draft of your -- I mean, if it is a general --

DR. O'SULLIVAN: I could give you the draft, yes.

DR. RARICK: Are there any specific issues you would want the committee to agree or not agree on?

DR. O'SULLIVAN: Well, two things. I think that under contraindications I have some concerns about things

like cardiac disease and insulin-dependent diabetics. I mean, there is no information regarding those entities. Obviously, these are entities that women might consider this procedure for.

DR. DAVIDSON: I think that is close to the objection -- the question that is being raised already. That should be included in the patient information.

DR. RARICK: Those of you with specific editing or wording suggestions, we would appreciate simply letting us have those suggestions so that we could take that under advisement. In this meeting, we would like you to think of expressing just sort of the general concept as Mary Jo and others have that you are concerned that the exclusion criteria somehow be reflected. We could then take that under advisement.

DR. DAVIDSON: At least the front part of her question is similar to the first advisory. You had others?

DR. O'SULLIVAN: Under the section where it talks about drug interactions and it says that in addition, drugs known to cause enzyme induction -- I am not quite sure I understand what that means. I think that that needs to be a little bit more specific.

DR. DAVIDSON: Okay.

DR. O'SULLIVAN: I have a lot that I would like to leave with Phil. But I guess I think that some of the

wording even in terms of the patient's part of that -- are we dealing with that too now?

DR. DAVIDSON: Yes.

DR. O'SULLIVAN: Even in terms of the patient's part of that, I was trying to read this both as a patient and as a physician. I think that there are things in here that ought to be worded differently.

DR. DAVIDSON: Well, actually, the patient part is number five.

DR. O'SULLIVAN: I could leave my comments with Phil.

DR. DAVIDSON: But, if you have any other generic ones that are more than just editing, then I think they ought to be raised.

DR. O'SULLIVAN: Yes, there is one other one. Under -- this is page 10. It says visit day three, the third paragraph under that. It says because of the risk of malformation of the embryo as a result of the treatment procedure patients who have an ongoing pregnancy at visit three must be prepared to have it terminated. But there is no information whatsoever about what the risk of malformation would be. I think that in order for somebody to be able to make a decision here about must be terminated, they ought to have some idea of what information, if any, is available. It should be in there.

DR. PETITTI: I had a similar comment on page 2 where there is a discussion of the teratogenicity studies. In fact, I think it should probably be made a little stronger in relationship to the embryo toxicity studies. It seems to me that the data from misoprostol strongly support the conclusion that it is a teratogen and that that is the reason for recommending that a pregnancy that continues after exposure to both mifepristone, misoprostol be terminated based on a probabilistic assessment that you cannot rule out the possibility of a congenital defect after that exposure. I think that it is a little weak the way it is written now and that is a generic comment both for the patient and the physician labeling.

DR. O'SULLIVAN: I do not think that we have the information to say that it is a teratogen.

DR. PETITTI: I think the animal data supports the conclusion that it is a teratogen. It is a pregnancy class D drug when given -- class X drug when given for its other indication.

DR. RARICK: It is X, right?

DR. PETITTI: X.

DR. O'SULLIVAN: But it is an X because there is absolutely not enough information. The only animal data we have is in rabbits -- the rats and rabbits. The monkeys -- I mean, there is very little of anything really except in

some rabbits.

DR. PETITTI: I think there is data from humans to suggest that it is also teratogenic in humans.

DR. RARICK: Excuse me. I think the misoprostol labeling that you are referring to -- is that what you are referring to?

DR. PETITTI: Yes, I am referring to misoprostol.

DR. RARICK: It has a boxed warning not to be used in pregnant women, but it is because it causes abortion, not because it is a teratogen. It is not a class X drug.

DR. PETITTI: That is a good clarification. I think I tried to ask that question.

DR. RARICK: And the data from Brazil on its use is not -- support the teratogenic.

DR. KESSLER: Why don't we -- and I know it is late -- Dr. Jordan, why don't you just go to the microphone, if you would? It is a very important point. The teratogenicity of misoprostol in laboratory animals -- what is on the labeling and what is known?

DR. JORDAN: Okay. On the labeling it says that it is not a teratogen for misoprostol; however, there are other data for other PGE1's that show that there is a possibility that it is a teratogen in rats, but I have not reviewed specifically that data. It is kind of new data.

But for misoprostol itself it says that it is not a teratogen.

DR. DAVIDSON: Unless you have captured this otherwise I think, and I want to repeat this for the committee, that regarding labeling for the physician and patient is that the committee is concerned that the cautions, and the conditions, and exclusions that were in the clinical trial protocol for information should also be included in the labeling and the patient information leaflet saying that there is no data as to what the effects would be with these associated conditions. Okay? And the recommendation for pregnancy termination should be worded in a way that it is an unknown specific risk but there is a risk. Since it is unknown, it is advisable that pregnancy termination occur if there is failure. I am restating that to see if that is what the committee is concerned about.

DR. O'SULLIVAN: I would say that it should it be considered, but would not say advisable.

DR. DAVIDSON: Well, say to be considered.

DR. HENDERSON: Or offered.

DR. DAVIDSON: Offered. In other words, they are seen as to be less demanding. Okay.

Are there any other concerns about questions four? Since we have talked about five these are labeling and informed consent questions. Are there any additional

concerns about four and/or five?

DR. AZZIZ: I have a concern with the section on dosage and administration. Under visit two day three of misoprostol administration there should be a comment there stating that, again, for information to the physician, the provider that the effectiveness of the misoprostol administration may decrease with a greater delay in its administration or its timing. We do not really know whether given three days later or four days later it is still or not effective. I think we should simply note there that the effectiveness of that may decrease.

DR. DAVIDSON: That emphasizes that point of the two-day dose.

DR. AZZIZ: Correct. But for the practitioner I think it is important to understand why that issue needs to be given that way. Because there is nothing here to indicate that that may become less effective.

DR. O'SULLIVAN: Why even select two days?

DR. AZZIZ: Yes. Why two days? I mean --

DR. DAVIDSON: Well, they said some of the synergy --

DR. AZZIZ: I understand that, but there is nothing in the physician label.

DR. DAVIDSON: Okay. It should be included in the labeling as to why there is that two-day limitation.

Okay. Anything else?

DR. ZONES: I alluded to this before, but I wanted clarification. In the provider labeling it lists chronic conditions about which there is very little information. I think that those should be itemized in the patient packaging.

DR. DAVIDSON: Yes, we said that.

DR. ZONES: Yes. Also, it says that you should report to your physician any drugs that you are taking. I think that you should list drugs, particularly aspirin and other common OTCs.

DR. DAVIDSON: Well, that is also included in the cautions and instructions that were in the clinical trial protocol.

DR. ZONES: I just want the patients to have the specific details because sometimes they catch stuff.

DR. DAVIDSON: We have requested that that be placed in both. Any other? Yes.

DR. PETITTI: I was myself on page six moderately confused about what one would do with the nursing mother. I think that this arises from the use of the regimen where misoprostol is not recommended for use by lactating women; but for mifepristone you have to decide whether or not to discontinue nursing or discontinue the drug. I think there is a contradiction there and it needs to be resolved.

DR. DAVIDSON: So, in essence, the advice would be that the regimen would not be commended for nursing mothers rather than dividing it this way?

DR. HENDERSON: Do we know whether it is stored? I mean, why can't they discard that milk for the two or three days and continue nursing? Why do they have to stop nursing?

DR. PETITTI: I am only saying that misoprostol --

DR. HENDERSON: But if they do not nurse while they are taking -- if they do not give the baby the milk while they are taking the medication, why could they not resume nursing after the termination if they are still producing milk? I do not know. I mean, I am just asking if that is --

DR. PETITTI: I am only saying that given that misoprostol is not recommended and it does not explain why it is not recommended for nursing women that the advice should be the same.

DR. DAVIDSON: Can you comment on this, Dr. Rarick?

DR. RARICK: I think we hear you that potentially we could work with the sponsor on that section of the labeling to either have it be consistent not to use it in lactating women or to tell lactating women to stop

lactating during its use.

[Laughter.]

PARTICIPANT: Turn on and turn off?

DR. RARICK: Do you understand what I mean? Stop breast-feeding.

DR. DAVIDSON: Either way would work.

[Laughter.]

DR. RARICK: To add to Dr. Petitti, I think the warning in the misoprostol is an actual label because it is a chronic-use labeling. So we will have to work with this sponsor with how we work on that section. Thanks for pointing that out.

DR. O'SULLIVAN: While you are on that page, too -- and I wrote a note about this -- pediatric use. It says safety and effectiveness in pediatric patients. Well, what is a pediatric patient? I mean, if pediatricians -- the adolescents and the pediatricians will tell you up to age 23. So somehow we are going to have to deal with that.

DR. RARICK: Right. The sponsors probably are trying to conform to our pediatric use guideline document, and so we will have to work with them again on that.

DR. DAVIDSON: Let me ask a question about another issue. Are you through with the lactation?

Efficacy diminishes with gestation age. Is there an appropriate emphasis as written that the decreasing

efficacy, which is a success of what 91 to 92 percent if it is near 49 days versus 97 percent of so if it is much earlier? Is that difference significant enough that it should have higher emphasis in the patient information leaflet? What about the people who conducted these studies?

DR. O'SULLIVAN: According to the data the drop-off is after 49 days.

DR. DAVIDSON: So that is not significant enough to be of any concern?

DR. BARDIN: It is a highly statistically significant observation; however, it does not make a lot of clinical difference as long as you stay below 49 days.

DR. DAVIDSON: Okay. All right.

DR. BARDIN: So I think that both statements are correct.

DR. DAVIDSON: Well, then we do not need to bother.

Are there any other comments or concerns in regard to four and five having to do with labeling and the patient information?

DR. NARRIGAN: I have just an unfortunate procedural -- I did not receive this document so I am going to abstain because I have not had a chance to review it.

DR. DAVIDSON: But this -- we are not going to

vote on these two. We are just raising issues.

DR. NARRIGAN: The labeling?

DR. DAVIDSON: Right.

DR. NARRIGAN: Oh, I am sorry. Okay. Thank you. I misunderstood.

DR. DAVIDSON: Well, let me read the question and see if we are responding. If the regimen were to be approved do you consider the labeling proposed by the applicant on how to administer the regimen and how to monitor patients who are receiving it to be appropriate? We are providing a lot of comments that have taken -- so we did not vote on it being approved. Is it necessary since we are giving you all of this other advice? So whatever -- but if you have any -- even in your present reading, if you have any questions or concerns, this would be the opportunity to raise them. Okay.

DR. RARICK: I think you are safe to answer the rest of the questions as commentary probably. Instead of voting and then commenting you might as well just give us the actual --

DR. DAVIDSON: Well, we were kind of going in that -- we tried to as much as possible do what we are instructed and requested.

[Laughter.]

Does someone have -- yes?

DR. PETITTI: I have just two other relatively minor comments -- well, one minor, and one major. I think that physician or the labeling should say written informed consent rather than informed consent. I think that most physicians are used to informed consent, but this is actually a specific requirement for written informed consent.

On the actual patient consent form where there is the part where people are going to be asked to sign, I would like to have something perhaps added that the physician has discussed alternatives -- just maybe a sentence: "My physician has discussed with me alternatives to medical abortion, including surgical abortion, continuation of the pregnancy." I wonder if perhaps since sometimes patients actually read these things and pay a lot of attention to them that there might be a statement that would say my doctor has confirmed that I am pregnant and that the pregnancy has not lasted for more than 49 days, or something that affirms that that patient sort of understands what the doctor told her.

DR. DAVIDSON: Okay. I think that that is a good point.

Any others in regard to four and five?

[No response.]

If not, are you ready to move to the next number

six? If the regimen were to be approved do you have recommendations concerning the drug distribution system proposed by the applicant? Now, that has to do with only a physician, the training involving pregnancy, dating, ectopic pregnancy identification and surgical evacuation of the uterus and the dispensation would be in the doctor's office or clinic. The drug would be provided directly to the provider.

DR. O'SULLIVAN: Again, I have a question.

DR. DAVIDSON: Yes?

DR. O'SULLIVAN: There are nurses who do abortions who are recognized to be able to do that. Are they countermanded from the opportunity to do this as part of the abortion services that they provide?

DR. DAVIDSON: Would someone from the Council like to answer that in terms of what intentions are?

DR. WINIKOFF: Use of the drug the way it is proposed has to be under the supervision of a qualified physician.

DR. O'SULLIVAN: So under the supervision? That is fine.

DR. DAVIDSON: That is what I thought. Yes.

DR. O'SULLIVAN: That is fine.

DR. DAVIDSON: Okay.

DR. AZZIZ: A point of interest, I think, for

information, I mean, those nurses have to have physician supervision at some level.

DR. O'SULLIVAN: I believe they are supposed to, yes.

DR. AZZIZ: So that would cover that.

DR. O'SULLIVAN: Well, I just wanted to make sure.

DR. DAVIDSON: Okay. All right. Are there any other questions about the proposed distribution system?

DR. O'SULLIVAN: The other question I have is how -- this recordkeeping that the physician is going to have to do -- that is exactly the same as the IUD record system? Is that exactly what you are proposing? It would be no different from the IUD recordkeeping system?

DR. WINIKOFF: It is precisely modeled on the IUD system. I think that in all of the largest elements it is the same. I cannot tell you that the actual forms are the same.

DR. O'SULLIVAN: My point is that it should be a simple as possible because in today's world with all of this stuff that doctors have to do in the office plus how fast they have to do it and how quickly they have to turn it over, and the amount of paperwork that they have to do it is getting to the point where you do more paperwork than you do patient work. It has got to be simplistic.

DR. WINIKOFF: I certainly appreciate that. I am sure that we do not want to encumber the physicians who are using the drug.

DR. O'SULLIVAN: It will stymie them from using it at all.

DR. DAVIDSON: All right. Are there any other suggestions or comments about six?

DR. RARICK: I would like some clarification. I am assuming that this would be distributed to any provider who requested it. But would there be some way of validating it?

DR. DAVIDSON: There were training and skill --

DR. RARICK: That was what I was wondering. How is that being evaluated?

DR. HENDERSON: Well, it would be like the Norplant system, I assume.

DR. RARICK: I have not heard that.

DR. DAVIDSON: How would physician and provider selection be operationalized?

DR. HENDERSON: Thank you. That is much better wording.

[Laughter.]

DR. WINIKOFF: The distributor will be the entity responsible for operationalizing the actual training of the physicians.

DR. HENDERSON: Who would?

DR. WINIKOFF: The distributor of the drug.

DR. HENDERSON: Meaning you?

DR. WINIKOFF: No. We are not the distributor.

DR. HENDERSON: Oh, I see.

DR. RARICK: Who is? As far as the validation that the physicians have appropriate training, the physicians will have to certify that they do. But there is proposed to have an examination of the physicians.

DR. ALLEN: My name is Dr. Susan Allen. I am the President of Advances in Health Technology. I am very pleased to be here today. My responsibility and the responsibilities of my organization will be to ensure that providers are trained and that the qualifications that you have heard discussed earlier today are met. Only physicians who have had training in how to administer the drug, how it works, what the side effects are, what the complications are, and how to manage those side effects and complications will be able to order and receive the drug.

DR. O'SULLIVAN: And how will you supervise that they have had experience in giving it?

DR. ALLEN: We will basically ensure that they have received that training. We are not going to go in and supervise every physician and watch them do it.

DR. O'SULLIVAN: That is what I am trying to

understand. You are going to bring physicians in to see that they know how to give the patient a pill?

DR. ALLEN: No. We are going to provide training for physicians throughout the country to ensure that they do know how the drug works, what it is about, how well it works, what the side effects are, and what the complications are, et cetera. But we are not going into every physician's office and watching them administer pills to women.

DR. O'SULLIVAN: Let me try it another way. Are you going to have meetings and seminars?

DR. ALLEN: Yes. We will be doing seminars throughout the United States.

DR. O'SULLIVAN: Well, now I have another question. If you are going to do these seminars, are you paying the physician to come to the seminar?

DR. ALLEN: No. We are not going to be paying the physician to come.

DR. O'SULLIVAN: I just wanted to make sure.

DR. RARICK: Dr. Allen, I think the question also is, okay, now you are going to be providing to those physicians only? Do you have to have records on them that they self-identify that they are trained?

DR. ALLEN: Yes. We will know which physicians have indeed been through the training program, yes.

DR. RARICK: Not just the training program, but they self-identify that they have training in surgical technique, that they have training in diagnosing an ectopic pregnancy, that they have training in the diagnosis of gestation. Those are some of the -- the provider requirements will be self-identified.

DR. ALLEN: Yes. We will ask them those questions. If you also recall when you go through medical school you learn how to date a pregnancy. You learn how to diagnose --

DR. O'SULLIVAN: No, no, no. That does not work that way.

DR. ALLEN: I disagree, but okay.

DR. DAVIDSON: I just want to caution you that you are looking at a table full of professors here.

DR. ALLEN: I know. I do respect that.

[Laughter.]

DR. KESSLER: Can I just ask on one point? In the slide that the Population Council showed it took careful introduction and distribution requirements. One of these things is physicians who have had training and then it listed three things. Is that only your training or does a board -- let's start with a board-certified obstetrician who has --

DR. ALLEN: Right.

DR. KESSLER: They do not have to take your training.

DR. ALLEN: That is right.

DR. KESSLER: They have to be able to certify that they have met this. But you will also offer training and then physicians can certify?

DR. ALLEN: The way that the training will be done -- it will be done in two phases. The first phase will be in providers who currently make surgical abortion services available so they already have those skills.

The second phase of training will be done in clinicians who do not currently make surgical abortion services available. And that will include training in manual vacuum aspiration. So there will be a component ensuring that physicians who do not right now provide surgical abortion services have some training in manual vacuum aspiration.

DR. AZZIZ: I have a comment. I think we are treading on very dangerous ground. One, we are trying to dictate medical practice which is not what we can do. Secondly, I think that it is an error and probably needs to be addressed now to train nonsurgeons to do a procedure which is a D&C on a pregnant uterus which is extremely risky.

Now, early on I asked the question whether the

same physician who administered mifepristone had to do the D&C if there was a failure? The answer was no. He or she had to have backup for that. So before you all get into deep water by training family practitioners who have never done surgical procedures to do a procedure that is complicated, I would simply readdress the issue. Do these physicians simply need to identify a backup surgeon in the event of a five percent failure rate in which case then the issue is resolved? I would like you to address that clearly because we are getting conflicting information.

DR. ALLEN: Well, first of all, I do think that it would be important for physicians who do not right now make surgical abortion services available to indeed identify clinicians who could provide backup services for them. I am not an OBGYN physician. I provided thousands of abortions in the United States and was trained in approximately two weeks time to perform instrumental evacuation of the uterus. I do not think it is necessarily appropriate to say that family practitioners, pediatricians, internists, et cetera, will not be able to make evacuation of the uterus a safe procedure. I think that it can be done.

DR. AZZIZ: My concern is that I would not tie this drug which we are considering to the training which is rather radical. I mean, you are a highly-motivated, very

intelligent person who wants to do this. That cannot be translated to a large population of physicians. So I would not tie what you just recommended to this drug approval process because I think that is wrong to do so.

DR. ALLEN: Point well taken. But I also do not think that -- every physician in this country is not going to want to make this drug available to women; but there will be many who do and they will want to acquire the skills that are appropriate to manage the side effects and complications.

DR. LEWIS: I have to agree with Dr. Azziz. I do not think you can teach somebody to do a surgical evacuation of the uterus in a simple seminar with a mannequin or something.

DR. HENDERSON: I think you can. You just cannot handle the complications.

DR. LEWIS: No. And you are talking about something that you would have to do in only five percent so you would do this actually infrequently in contrast to yourself. It is not that the person is a family practitioner or an intern, it is also the frequency with which they do those procedures. So, if you are talking about in an emergency situation having the skill to be able to do this deftly, appropriately, and with minimal complication, such a person who has never been trained in

that and who has only attended a seminar is the worst possible choice of person to do that. They should have a surgeon available as backup.

DR. ALLEN: Again, point well-taken. I think the other thing when I mentioned that there would be two phases of training, the two phases will also be very different. The first phase of training in which you have providers who currently make surgical abortion available will have to be much less intensive because they already have the skills. When you talk about the second phase of training, and you are taking on not just a didactic session but a practicum session as well, it is not something that will probably be able to be done in a day. It may take a few days. It may take observation and participation by those particular clinicians in a clinic that right now makes those surgical abortion services available.

DR. AZZIZ: Again, I am confused. Your training of nonsurgeons to do procedures surgically in two weeks' time is a radical and I think very interesting approach. Is this what the committee is being asked to look at or not? Because originally we never thought this was. I think this is why I am concerned that this is getting involved. We are simply going to ask physicians to identify a backup if they do not do the procedures at this point.

DR. ALLEN: This is not to my understanding a part of the labeling that you will be reviewing. I do not think that you are being asked to approve that.

DR. DAVIDSON: But we are being asked to comment on the distribution system. This is part of what is being proposed.

DR. KESSLER: And it is our understanding that the distribution system will be a part of the labeling.

DR. RARICK: Essentially.

DR. DAVIDSON: Right. I think what you are hearing from the committee as the issue of skills being discussed, there is considerable unease about how that certification and documentation is going to be done to ensure safe delivery of this regimen and management of its complications.

DR. ALLEN: Point taken.

DR. DAVIDSON: I think that it is a comment that the committee is just --

DR. RARICK: Let me ask the question a different way, Dr. Davidson. Does the committee agree with the concept that the distribution system of provider certification providing only to providers who are certified and that they have training in blah-blah, and blah, is that something that you can live with as the restricted distribution system -- that we will work further as to how

that is going to be verified, confirmed, or is there anything else you would want to add?

DR. DAVIDSON: We may want to take a vote on that -- whether or not that we agree in concept with the proposed distribution but we have some serious reservations about how it is currently described in terms of assuring safe and adequate credentialling.

DR. AZZIZ: But just to bring it back again. The labeling currently proposed does not bring in any of these concerns that we have just been sprung on.

DR. DAVIDSON: That is the reason why -- so would you want to vote on what I have just said that we agree in concept with the proposed distribution but we have serious concerns about how certification of the skills is presently described?

DR. RARICK: I do not think that you need to vote on that, Dr. Davidson.

DR. DAVIDSON: We do not?

DR. RARICK: I think we hear that comment.

DR. DAVIDSON: Oh, okay.

DR. RARICK: If everybody agrees?

DR. DAVIDSON: So you just took a vote.

DR. RARICK: I am sorry.

[Laughter.]

DR. RARICK: You can go right ahead and vote.

[Laughter.]

DR. DAVIDSON: Well, since we voted, anyway, all in favor of that, raise your hands.

[There was a show of hands and the motion was approved unanimously.]

DR. DAVIDSON: Unanimous.

Finally, postmarketing.

DR. HENDERSON: I think the distribution system should be monitored postmarket -- in the postmarket study.

DR. DAVIDSON: The first suggestion is that the distribution system should be monitored postmarket.

[Laughter.]

DR. KESSLER: But, Dr. Henderson, you have a little conflicting recommendation. You want to keep records simple. Now, are you saying that every physician who administers this should be involved in postmarket surveillance and that is a requirement of participating?

DR. HENDERSON: I think we should monitor complications in the postmarket survey, that is surgical complications -- complications from failed terminations from the medical therapy. That is what I am most concerned about.

DR. KESSLER: Survey or 100 percent of every physician who participates?

DR. HENDERSON: Reporting surgical complications

following this medical procedure.

DR. KESSLER: For every physician who participates?

DR. HENDERSON: Should report surgical complications.

DR. O'SULLIVAN: Could another way of asking that or another way of dealing with that be that those physicians who are already credentialed to do this either in hospital facilities, ambulatory care facilities, or by the departmental chairman would not have to do that, but those who are not credentialed in that manner would have to do that?

DR. DAVIDSON: That is one way. There are various ways to look at that distribution. Because in instances where there are already clinical privileges being monitored in this regard, there may be less of a need in terms of looking at the skill question.

DR. AZZIZ: Yes, just a comment again. I think you are right, Dr. Kessler. You do not want to make it over-burdening, but you do need some information. I think that segregating out as to whether it is a university doc or an OBGYN-certified would be unfair to our family practice internal medicine colleagues who we want to encourage to use the drug if it is approved.

I think a time-limited survey of six months, a

year, two years, across-the-board, everybody using would be a much more useful thing. Because we may find out that family practice with a good OBGYN backup may do better than some OBGYNs who think that they can take care of everything. So these are issues that I think would be better just on a timeline survey, a year, six months, or whatever.

DR. O'SULLIVAN: You have also got to recognize one thing when you do that -- that the guy who is the backup will be also taking care of the complication of the other one. So this is something that I can tell you for board exams. So you know you examine candidates for boards and then you look at this big, huge list of complications, and you find out that this is the backup to two or three other people and he has the complications.

DR. KESSLER: Dr. Davidson, may I just ask -- we appreciate your advice. The sponsor is here. I was wondering whether the sponsor would be willing to commit generally to this kind of advice?

DR. ARNOLD: Yes. We are willing to discuss it.

DR. DAVIDSON: Oh.

DR. KESSLER: We take that as a yes.

[Laughter.]

DR. DAVIDSON: Are there any other post-marketing suggestions or concerns?

[No response.]

A couple I have heard before and that is some way of looking at long-term probably following some subpopulation to look at long-term effects of both single and multiple use would be helpful.

DR. DALING: I think we need to document how many women actually come back for all three visits.

DR. HENDERSON: Incomplete treatment.

DR. DALING: For the three treatments, especially the second.

DR. DAVIDSON: All right.

DR. DALING: And what the loss to follow-up actually is.

DR. DAVIDSON: Okay. The other is, as possible, the experience over age 35 --

DR. HENDERSON: Who smoke.

DR. DALING: And under 20.

DR. DAVIDSON: -- who smoke.

PARTICIPANT: Under 20?

DR. DAVIDSON: Because although there are cautions here, there clearly are people who both the physician and the patient may accept this on certain risk in these categories. To the extent that it could be documented it would be helpful. Some of the clinics or et cetera may have that. Okay.

DR. AZZIZ: I think it will be very important to keep a record and maintain a record of pregnancies who have received mifepristone, for example, and continued it. Because, clearly, we do need -- that will be a major question in three or four years and we need that.

DR. DAVIDSON: Okay. Anything else?

[No response.]

I do not have any other questions. So, if there is nothing else, are there any final comments or anything else we need?

Oh, one thing. We have some committee members who are departing. That was over the microphone.

[Laughter.]

We can do this quickly. Dr. Corfman has provided us with some certificates documenting your participation on the committee for Drs. Henderson, Daling, and Dr. Zones.

DR. ZONES: Thank you.

[Applause.]

DR. DAVIDSON: On that note, we will adjourn.

[Whereupon, the meeting was adjourned at 6:38 p.m.]